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IN THE

Supreme Court of the United States

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as SCIMED LIFE SYSTEMS, INC.),

Petitioners,

v.

CORDIS CORPORATION,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Congress enacted the *ex parte* patent reexamination statute for the limited purpose of permitting the Patent Office to review a granted patent where "a substantial new question of patentability" is raised by prior art. 35 U.S.C. § 303. The statute implements this limited purpose by providing that a patent owner may amend an existing claim in the patent or submit a new claim during reexamination, but only if the amended or new claim is submitted in order to distinguish the prior art or responsing to a decision adverse to patentability, and does not broaden the claim scope. 35 U.S.C. § 305.

In its decision below, the Federal Circuit sanctioned a patent owner's abuse of a reexamination proceeding that it initiated for the improper purpose of advancing its position in parallel patent infringement litigation—in two ways. First, the Federal Circuit held that the patent owner could broaden the meaning of the claim language from the meaning set forth in the original patent, in order to better cover the accused product, by introducing self-serving and *ex post facto* attorney prosecution arguments and extrinsic evidence. Second, the Federal Circuit held that the patent owner could submit a new claim not for the permitted purpose of distinguishing the prior art or responding to an adverse patentability decision, but rather solely for the purpose of better covering the accused product in the litigation.

The question presented is:

Whether a patent litigant should be allowed to bolster its position in an ongoing patent infringement litigation by simultaneously initiating an *ex parte* reexamination proceeding on the patent-in-suit, and then, in violation of the limited purpose of the reexamination statute and the clear language of 35 U.S.C. § 305: (a) by relying on self-serving and *ex post facto* attorney prosecution arguments and extrinsic evidence made in the *ex parte* reexamination to broaden the meaning of the claim language in the litigation; and (b) by adding a new claim to the patent-in-suit by amendment in the reexamination, not for the purpose of distinguishing prior art or responding to an adverse patentability decision, as the statute permits, but solely for the improper purpose of more specifically covering the accused product in the litigation?

PARTIES TO THE PROCEEDINGS

Petitioners Boston Scientific Corporation and Boston Scientific Scimed, Inc. (formerly known as Scimed Life Systems, Ltd.) (collectively, "BSC") were two of the three defendants-appellants in the Court of Appeals for the Federal Circuit and the District Court for the District of Delaware. The other defendant-appellant was Medtronic Vascular, Inc. Respondent Cordis Corporation ("Cordis") was the plaintiff-cross-appellant in the Federal Circuit and the District of Delaware.

CORPORATE DISCLOSURE STATEMENT

Boston Scientific Corporation is the parent corporation of Boston Scientific Scimed, Inc. There are no other parent corporations and/or publicly held companies that own 10 percent or more of the stock of Boston Scientific Corporation or Boston Scientific Scimed, Inc.

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Petitioners Boston Scientific Corporation and Boston Scientific Scimed, Inc. hereby respectfully petition for a writ of certiorari to reverse the judgment of the United States Court of Appeals for the Federal Circuit that (a) claim 23 of the patent-in-suit is infringed, and (b) claim 44 of the patent-in-suit is not invalid.

OPINIONS BELOW

The opinion of the Court of Appeals for the Federal Circuit is reported at *Cordis Corp. v. Medtronic AVE, Inc.*, 511 F.3d 1157 (Fed. Cir. 2008), which is reproduced in the Appendix ("App.") at 1a-57a. The opinions of the District Court for the District of Delaware are reported at *Cordis Corp. v. Medtronic AVE, Inc.*, 336 F. Supp. 2d 363 (D. Del. 2004), which is reproduced at App. 58a-74a, and *Cordis Corp. v. Medtronic AVE, Inc.*, 194 F. Supp. 2d 323 (D. Del. 2002), which is reproduced at App. 75a-176a.

JURISDICTION

The Court of Appeals for the Federal Circuit entered judgment on January 7, 2008. App. 1a-57a. The Court of Appeals denied a timely combined petition for panel rehearing and rehearing *en banc* on April 9, 2008. App. 177a-183a. Petitioners invoke this Court's jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS

This case concerns the *ex parte* patent reexamination statute, 35 U.S.C. §§ 301 to 307, and, in particular, section 305, which provides as follows:

> **35 U.S.C. § 305 – Conduct of reexamination proceedings.**
>
> After the times for filing the statement and reply provided for by section 304 of this title have expired, reexamination will be conducted according to the procedures established for initial examination under the provisions of sections 132 and 133 of this title. In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301 of this title, or in response to a decision adverse to the patentability of a claim of a patent. No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter. All reexamination proceedings under this section, including any appeal to the Board of Patent Appeals and Interferences, will be conducted with special dispatch within the Office.

STATEMENT OF THE CASE

I. Congress Enacted the *Ex Parte* Patent Reexamination Statute for the Limited Purpose of Permitting the Patent Office To Review Granted Patents in Light of Prior Art

This petition raises for the first time in this Court an important question about the proper scope and interpretation of the *ex parte* patent reexamination statute, 35 U.S.C. §§ 301-307. Congress enacted this statute in 1980 for the limited purpose of permitting the Patent Office to review a granted patent where "a substantial new question of patentability" is raised by prior art. 35 U.S.C. § 303; *In re Etter*, 756 F.2d 852, 856-57 (Fed. Cir. 1985) (*en banc*). The House Report in support of the legislation explained that it was designed to "strengthen[] investor confidence in the certainty of patent rights by creating a system of administrative reexamination of doubtful patents," which would "permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation." H.R. Rep. No. 96-1307, at 3 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6462.

Section 305 of the reexamination statute implements this limited purpose of reexamining the patentability of issued patents in view of prior art by strictly limiting the ability of the patent owner during reexamination to amend existing patent claims or add new claims, in two respects. First, an amended or new claim must be submitted in order to distinguish the prior art or in response to a decision by the Patent Office that is adverse to patentability. Second, an amended or new claim also must be narrower than the original claim

scope. The relevant text of section 305 provides as follows:

> In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301 of this title, or in response to a decision adverse to the patentability of a claim of a patent. No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter.

35 U.S.C. § 305.

In view of both of these express restrictions on the ability of a patent owner to submit amended or new claims, it is clear that Congress did not intend *ex parte* reexamination proceedings to be used by patent owners as a vehicle for continued patent prosecution or a belated substitute for reissue prosecution, where such restrictions do not apply.[1] Yet that is precisely what the patent owner, Cordis, did in this case. It went back to the Patent Office almost a decade after the patent had issued, and, while this litigation was underway, initiated and conducted an *ex parte* reexamination in which it prosecuted amended and new claims in order to better

---

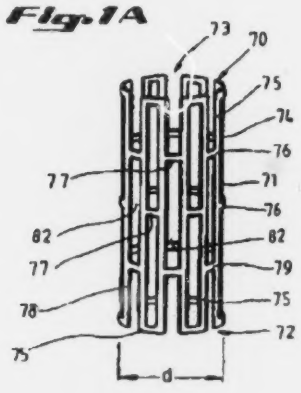
[1] Neither ordinary continuation practice nor the reissue statute limits the submission of amended or new claims to submission for the purpose of distinguishing the prior art or responding to adverse patentability decisions, and both permit broadening the claim scope (albeit only within two years after issuance for a reissue (*see* 35 U.S.C. § 251, ¶ 4)).

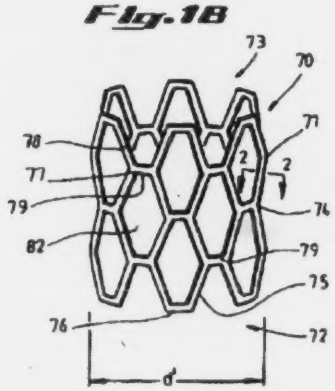
cover BSC's accused NIR stent and bolster its position in the litigation.

II. Cordis Abused the *Ex Parte* Reexamination Procedure by Initiating a Reexamination in Parallel with this Litigation and then Relying in the Litigation on Improper New Claims and Broadening Arguments Submitted During the Reexamination

This patent case relates to a specific design for a balloon-expandable stent. A balloon-expandable stent is a tiny mesh-like structure which is placed on a balloon catheter, intraluminally delivered on the catheter through the vascular system to a blockage in a blood vessel, expanded by the balloon, and left in place to dilate and scaffold the vessel and improve blood flow.

The patent-in-suit in this case is U.S. Patent No. 4,739,762 (the "'762 patent"). The '762 patent describes and claims a specific design for a balloon-expandable stent, namely the "slotted-tube" stent shown in Figures 1A (unexpanded) and 1B (expanded) of the patent (shown below), which the patent describes as preferably being made by cutting staggered slots into a cylindrical, metal tube.





The two claims of the '762 patent at issue in this case are claims 23 and 44. Claim 23 is an apparatus claim, which recites details of the slotted-tube structure shown in Figures 1A and 1B. It is a dependent claim which depends from independent claim 13. Claim 13 recites, *inter alia*, an "expandable intraluminal vascular graft" that comprises a "thin-walled" "tubular member" that has a "wall surface" with a "plurality of slots formed therein." Dependent claim 23 adds the additional limitation that the "outer surface" of the tubular member must be a "smooth surface" when the tubular member is in its unexpanded state (*i.e.*, during delivery but before expansion). The claim language and the specification of the '762 patent do not contain any text that explains the meaning of the word "smooth surface" in claim 23. The patent merely describes how the tubular member shown in Figure 1A is preferably made from a cylindrical, metal tube. As is evident from Figure 1A, that tube has a perfectly smooth outer surface.

Unlike claim 23, which formed part of the original '762 patent when it issued in 1988, claim 44 is a new claim that Cordis added ten years later during the reexamination proceeding that it initiated and conducted in parallel with this litigation. Claim 44 is a method claim, which recites, *inter alia*, the placement of the slotted-tube stent of Figure 1A (a "tubular member" with a "plurality of slots formed therein") on a balloon catheter, followed by the delivery and expansion of the stent to treat a blockage (stenosis) in a coronary artery.

In 1997, shortly after Cordis filed its complaint in this case alleging that BSC's NIR stent infringed the

'762 patent, and almost twelve years after the inventor filed his original patent application, Cordis sought to gain a tactical advantage in this litigation by initiating and conducting in parallel an *ex parte* reexamination of the '762 patent in the Patent Office.

A. Cordis Relied on Self-Serving and *Ex Post Facto* Attorney Prosecution Arguments in the Reexamination To Broaden the Scope of Original Claim 23 in the Litigation in Order To Ensnare BSC's Accused NIR Stent

During the reexamination, the Patent Office rejected many of the original claims of the '762 patent, including original claims 13 and 23, as not being patentable in view of new prior art, including a prior art patent to Ersek (U.S. Patent No. 3,657,744) ("Ersek"). Ersek describes a device that is virtually identical to the structure described and claimed in the '762 patent, but which is used differently, namely, as an expandable fixation sleeve used to hold and seal an aortic graft or heart valve. Like the claimed stent, Ersek's sleeve is an expandable tubular metal mesh with staggered slots.

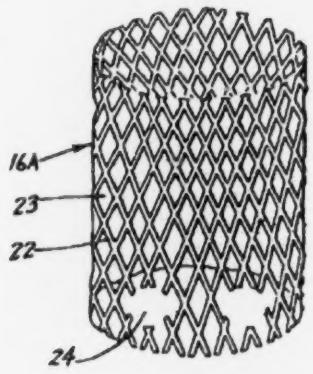


FIG. 2

In response to the rejection, Cordis' attorney cancelled claim 13, thereby conceding that it was not patentably distinct over Ersek. He then sought to confirm the patentability of other claims, including claim 23, by amending certain claims to add the "smooth surface" limitation and then relying on this limitation to distinguish Ersek on the ground that it did not disclose a "smooth surface" because of its bumpy outer surface (shown below in partial cross-section).

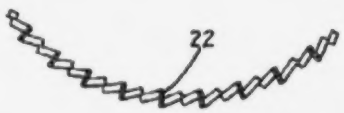


FIG. 5

Specifically, Cordis' attorney argued that the term "smooth surface" meant that the outer surface of the tubular member had to be smooth enough to intraluminally deliver. He then sought to distinguish Ersek on the ground that it purportedly was not smooth enough to intraluminally deliver. In support of this argument, Cordis' attorney submitted a declaration by a vascular surgeon, George Andros (who also served as an expert witness for Cordis in this litigation), which endorsed this definition of "smooth surface." Based on the *ex parte* submissions of Cordis' attorney and its litigation expert, the Patent Office confirmed the patentability of claim 23 on the ground that Ersek did not have a "smooth surface" and issued the reexamination certificate. *See* App. 40a-45a.

Neither Cordis' attorney nor Dr. Andros ever referred to the specification or the original prosecution of the '762 patent in support of their newly proposed definition of "smooth surface" during the reexamination. This is not surprising, since, as explained above, the '762 patent nowhere defines this term to mean smooth enough to intraluminally deliver. To the contrary, it implicitly defines the term to mean the perfectly smooth surface of the cylindrical, metal tube shown in Figure 1A.[2]

In other words, Cordis exploited the reexamination proceeding to broaden the meaning of "smooth surface" (and therefore the scope of claim 23) from the narrower meaning disclosed in the original patent, by introducing self-serving and *ex post facto* attorney prosecution arguments and extrinsic evidence.

B. Cordis Submitted New Claim 44 During the Reexamination Not for the Permitted Purpose of Distinguishing the Prior Art or Responding to an Adverse Patentability Decision But Rather Solely for the Improper Purpose of More Specifically Covering BSC's Accused NIR Stent

Cordis also used the parallel reexamination proceeding to submit new claims, including claim 44.

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[2] This definition from the specification is narrower than the definition propounded by Cordis' attorney and Dr. Andros. Although a stent that is perfectly smooth like the stent of Figure 1A will be smooth enough to deliver, the inverse is not true, because a stent (such as BSC's accused NIR stent) that is smooth enough to deliver may not be perfectly smooth.

However, in violation of section 305, it did not submit these new claims (claims 44 to 59) in order to distinguish the prior art or in response to a decision adverse to patentability. Instead, it submitted the new claims as an afterthought to its substantive response to the examiner's rejection of the original claims (claims 1 to 43), and explained to the examiner that the new claims were being submitted to cover competitive products and methods:

> Claims 1, 13, 24, 35 and 37 have been amended in accordance with the discussions with Examiner Thaler at the above-noted interviews, and in subsequent telephone discussions on July 13, 1998.[3] *Added claims 44-59* are all narrower in scope than the original claims, and *provide specific protection for aspects of the disclosed invention which have been incorporated into competitive products and methods.*
>
> As discussed with Examiner Thaler on July 17 and 21, 1998, the subject matter of claims 44-59 is fully supported by the written description of the invention and the drawings of the '762 patent and does not raise any new matter issues.

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[3] As stated in this passage, Cordis initially amended claim 13 and cancelled claim 23 before it later rescinded that cancellation and instead cancelled claim 13. However, both of these procedural alternatives had the same effect of expressly relying for patentability on the "smooth surface" limitation added by claim 23 and conceding that the remaining combination of features in claim 13 is not patentable.

C.A. App. A2041-42 (emphasis added). The above statements are the only statements Cordis' attorney (or Dr. Andros) made about claim 44 in the entire reexamination prosecution history. They made extensive arguments that original claims 1 to 43 were patentable over the prior art, including Ersek, but they never referred to claim 44 as distinguishing the prior art or relating in any way to the examiner's prior rejection.

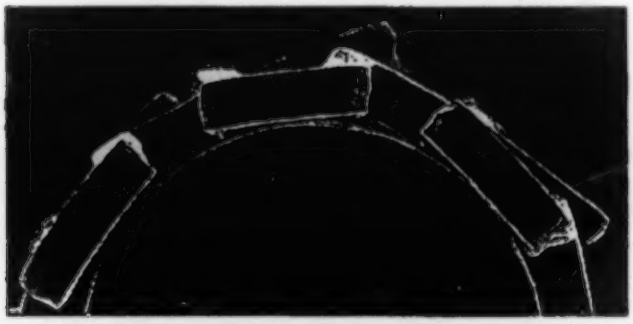
After the examiner allowed claim 44 and the reexamination certificate issued in 1998, Cordis added the reexamination certificate to this litigation and asserted claim 44, along with claim 23, against BSC at trial.

III. The Federal Circuit Sanctioned Cordis' Abuse of the Reexamination Procedure and Ignored the Limited Purpose and Clear Language of the Reexamination Statute

A. The Federal Circuit Reversed the District Court's Claim Construction of "Smooth Surface" and Thereby Broadened the Scope of Original Claim 23 Based Solely on Cordis' Self-Serving and *Ex Post Facto* Attorney Prosecution Arguments Submitted During the *Ex Parte* Reexamination

As part of its claim construction ruling prior to trial, the District Court correctly defined the claim term "smooth surface" in claim 23, consistent with Figure 1A, to mean "[t]he outside of the wall surface of the unexpanded tubular member has a 'continuously even surface, without roughness, points, bumps or ridges,

especially to the touch.'" App. 86a; *see generally Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). BSC relied on this claim construction at trial to argue that its accused NIR stent did not literally infringe claim 23 because its bumpy surface (shown below in a partial end-view of a NIR stent mounted on a mandrel) is not "continuously even" and "without roughness, points, bumps or ridges . . . ."



The jury found no literal infringement of claim 23. However, the jury did find infringement of claim 23 under the doctrine of equivalents. *See generally Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997).

In its post-trial motions, BSC argued that the NIR stent could not infringe the "smooth surface" limitation under the doctrine of equivalents as a matter of law because Cordis' arguments and amendments to distinguish Ersek during the reexamination gave rise to prosecution history estoppel. *See generally Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002). The District Court initially declined to decide the amendment-based prosecution history

estoppel issue. App. 119a-120a n.16; *id.* at 124a-125a.[4] However, it later held that prosecution history estoppel under *Festo* did not apply to limit the range of equivalents for the "smooth surface" limitation because the rationale for Cordis' amendments adding this limitation to distinguish the bumpy surface of Ersek during the reexamination were purportedly "tangential" to the allegedly equivalent bumpy surface of BSC's NIR stent. *Id.* at 71a-74a.

On appeal to the Federal Circuit, BSC vigorously challenged the District Court's ruling that Cordis' amendments were merely "tangential" and argued for JMOL or a new trial on the ground that the District Court had erred by failing to instruct the jury that prosecution history estoppel limited the range of equivalents for the "smooth surface" limitation. At Cordis' urging, the Federal Circuit avoided the need to decide whether *Festo* applied and side-stepped BSC's prosecution history estoppel arguments, by reversing and broadening the District Court's claim construction of "smooth surface" and relying on the new construction to find literal infringement. Specifically, the Federal Circuit concluded, based solely on Cordis' *ex parte* submissions during the reexamination that Cordis initiated and conducted in parallel with this litigation, that Cordis had defined the term "smooth surface" to

[4] Although the District Court initially declined to decide whether amendment-based prosecution history estoppel applied to the "smooth surface" limitation, it did decide that argument-based prosecution history estoppel applied to a different limitation in claim 23, namely, the "substantially uniform thickness" limitation, and subsequently ordered a new trial of infringement of that limitation only.

mean smooth enough to intraluminally deliver. The Federal Circuit proceeded *sua sponte* to grant Cordis summary judgment of literal infringement of claim 23, thereby avoiding entirely the *Festo* and doctrine of equivalents issues. *Id.* at 40a-45a.

The Federal Circuit did not consider whether this broad definition of "smooth surface" was consistent with the meaning that can be gleaned from the specification or original prosecution of the '762 patent. Indeed, it did not even refer to the patent specification, but instead relied solely on the self-serving and *ex post facto* attorney prosecution arguments and extrinsic evidence that Cordis submitted during the reexamination that it conducted more than twelve years after the inventor filed his original patent application and while this litigation was already underway.

B. The Federal Circuit Reversed the Findings by the Jury and the District Court that New Claim 44 Did Not Comply with Section 305 Because It Was Submitted Solely for the Improper Purpose of Covering BSC's Accused NIR Stent, and Instead Ruled that Section 305, Despite Its Clear Language to the Contrary, Does Not Limit the Purposes for Which a New Claim May Be Submitted

BSC also asserted at trial that claim 44 was invalid because it failed to comply with 35 U.S.C. § 305. Specifically, BSC asserted that claim 44 did not comply with the statutory requirement that a new claim had to be submitted in order to distinguish the prior art or in response to a decision adverse to patentability, because

Cordis had affirmatively told the Patent Office only that it had submitted claim 44 to cover competitive methods and products. The jury agreed with BSC and returned a verdict that claim 44 was invalid. App. 102a. After Cordis moved for JMOL, the District Court decided to treat the question as a question for the Court, but then came to the same conclusion as the jury, based on Cordis' admission in the reexamination prosecution history. *Id.* at 134a-138a.

On appeal, at Cordis' urging, the Federal Circuit reversed the judgment of invalidity, holding that the District Court had "incorrectly interpreted section 305." *Id.* at 53a-56a. The Federal Circuit ignored the plain language of section 305 and held that the only "substantive limitation" in the section is the prohibition against broadening claim scope. It read the requirement that a new claim must be submitted to distinguish the prior art or in response to a decision adverse to patentability out of the statute by making this requirement superfluous, concluding that "if the claims fail to distinguish the prior art, the claims will be rejected on the appropriate grounds." *Id.* at 56a.[5]

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[5] The Federal Circuit also concluded that Cordis had submitted new claim 44 in response to the examiner's rejection of the original claims, based solely on the superficial fact that Cordis had added claim 44 in the same paper in which it responded to the rejection, even though Cordis did not argue in that paper (or any other paper) that claim 44 was patentable or that it distinguished the prior art cited in the rejection. *Id.* at 55a.

REASONS FOR GRANTING THE PETITION

The Court should grant the petition because the Federal Circuit's decision upsets the balance between patent protection and legitimate competition. A competitor should be able to rely on the public record of the original patent and its prosecution in order to make investment decisions. The Federal Circuit's decision unfairly favors patent owners at the expense of competitors because it permits a patent owner to return to the Patent Office years after the patent has issued and exploit the Patent Office's *ex parte* procedures to broaden its claims and submit new claims in order to strengthen its position in a parallel infringement litigation. This tactic is not what Congress enacted the reexamination statute for, and this Court should take this opportunity to restore the balance that has been upset by the Federal Circuit.

I. The Federal Circuit's Decision To Permit a Patent Owner To Broaden the Meaning of the Claim Language from the Meaning Set Forth in the Original Patent Specification During Reexamination Is Contrary to the Limited Purpose and Language of the Reexamination Statute and Is Contrary to this Court's Precedent

The first reason why the Court should grant the petition is because the Federal Circuit's decision to permit a patent owner to initiate and conduct an *ex parte* reexamination proceeding to broaden the meaning of the claim language from the meaning set forth in the original patent specification is inconsistent with the

purpose and language of the reexamination statute, and with this Court's precedent on claim construction in patent cases.

A. The Federal Circuit's Decision Is Inconsistent with the Limited Purpose of the Reexamination Statute and the Clear Language of Section 305 Which Prohibits Broadening the Claim Scope

The Federal Circuit's decision is inconsistent with the purpose of the reexamination statute. Congress enacted the statute for the limited purpose of permitting the Patent Office to review a granted patent where "a substantial new question of patentability" is raised by prior art. 35 U.S.C. § 303. It did not enact the statute to permit a patent owner to return to the Patent Office years after the patent has issued to broaden the claim language in order to better cover a competitor's product in a parallel infringement litigation. Indeed, the entire point of the reexamination statute is to discourage patent litigation, not to encourage or facilitate it.

The reexamination statute implements this limited purpose by providing that a patent owner may submit an amended or new claim during reexamination only if it does not broaden the claim scope. 35 U.S.C. § 305 ("No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter."). The Federal Circuit's decision is inconsistent with this statutory prohibition because it permitted Cordis to broaden the meaning of the term "smooth surface" (and therefore the scope of claim 23) from the original meaning set forth in the original patent specification.

B. The Federal Circuit's Decision Is Inconsistent with this Court's Precedent that the Prosecution History Must Not Be Used To Enlarge or Vary the Meaning of the Claim Language Set Forth in the Original Patent Specification

The Federal Circuit's decision is also inconsistent with long-standing precedent of this Court regarding claim construction in patent cases, which holds that statements by the patentee during prosecution may not be used to enlarge or vary the meaning of the claim language set forth in the description of the invention in the patent specification.

As this Court stated in *Markman*, the scope of a patent claim must be clearly defined so that the public can ascertain the metes and bounds of the monopoly. *See* 571 U.S. at 373 ("It has long been understood that a patent must describe the exact scope of an invention and its manufacture to 'secure to [the patentee] all to which he is entitled, [and] to apprise the public of what is still open to them.' " (citing *McClain v. Ortmayer*, 141 U.S. 419, 424, 12 S. Ct. 76, 77, 35 L. Ed. 800 (1891))).

As the Federal Circuit sitting *en banc* recently noted (in a different case), this Court has for over 150 years consistently held that the claim language must be interpreted in light of the patentee's description of the invention in the specification:

> That principle has a long pedigree in Supreme Court decisions as well. *See Hogg v. Emerson*, 47 U.S. (6 How.) 437, 482 (1848) (the

> specification is a "component part of the patent" and "is as much to be considered with the [letters patent] in construing them, as any paper referred to in a deed or other contract"); *Bates v. Coe*, 98 U.S. 31, 38 (1878) ("in case of doubt or ambiguity it is proper in all cases to refer back to the descriptive portions of the specification to aid in solving the doubt or in ascertaining the true intent and meaning of the language employed in the claims"); *White v. Dunbar*, 119 U.S. 47, 51 (1886) (specification is appropriately resorted to "for the purpose of better understanding the meaning of the claim"); *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 217 (1940) ("The claims of a patent are always to be read or interpreted in light of its specifications."); *United States v. Adams*, 383 U.S. 39, 49 (1966) ("[I]t is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention.").

Phillips v. AWH Corp., 415 F.3d 1303, 1315-16 (Fed. Cir. 2005) (*en banc*).

Moreover, as early as 1880, this Court emphasized that although statements made by the patentee during the prosecution of the application may be used to "confirm" the meaning of the claim language gleaned from the specification, they may not be used to "enlarge, diminish, or vary" that meaning:

> This construction of the patent [based on the claim language and the patent specification]

> is *confirmed* by the avowed understanding of the patentee, expressed by him, or on his half, when his application for the original patent was pending. We do not mean to be understood as asserting that any correspondence between the applicant for a patent and the Commissioner of Patents can be allowed to *enlarge, diminish, or vary* the language of a patent afterwards issued. Undoubtedly a patent, like any other written instrument, is to be interpreted by its own terms. But when a patent bears on its face a particular construction, inasmuch as the specification and claim are in the words of the patentee, it is reasonable to hold that such a construction may be *confirmed* by what the patentee said when he was making his application.

Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227 (1880) (emphasis added).

The Federal Circuit's decision to permit Cordis to broaden the meaning of "smooth surface" from the meaning set forth in the original patent specification, based solely on self-serving and *ex post facto* attorney prosecution arguments and extrinsic evidence submitted by Cordis during the *ex parte* reexamination, is inconsistent with this precedent. This Court should grant the petition to reaffirm its precedent that the prosecution history cannot be used to "enlarge, diminish, or vary" the meaning of the claim language set forth in the original patent, especially during a

reexamination proceeding initiated and conducted by the patent owner in parallel with infringement litigation many years after the patent has issued.

II. The Federal Circuit's Decision To Permit a Patent Owner To Submit a New Claim During Reexamination for a Purpose Other Than To Distinguish the Prior Art or To Respond to an Adverse Patentability Decision Is Contrary to the Limited Purpose and Language of the Reexamination Statute

The second reason why the Court should grant the petition is because the Federal Circuit's decision to permit a patent owner to submit a new claim during reexamination for a purpose other than to distinguish prior art or to respond to an adverse patentability decision is inconsistent with the purpose and language of the reexamination statute.

A. The Federal Circuit's Decision Is Inconsistent with the Limited Purpose of the Reexamination Statute and the Clear Language of Section 305 Which Requires a New Claim To Be Submitted To Distinguish the Prior Art or To Respond to an Adverse Patentability Decision

The Federal Circuit's decision to permit Cordis to submit new claim 44 for a reason other than to distinguish prior art is inconsistent with the plain language of section 305, which provides that an amended or new claim may be submitted only to distinguish the

prior art or in response to a decision adverse to patentability:

> In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301 of this title, or in response to a decision adverse to the patentability of a claim of a patent.

35 U.S.C. § 305.

Cordis submitted claim 44 not to distinguish the prior art or in response to a decision adverse to patentability, but rather, as its attorney told the examiner in the reexamination prosecution history, "to provide specific protection for aspects of the disclosed invention which have been incorporated into competitive products and methods." C.A. App. 2041-42. As the statute plainly provides, this is not a permitted purpose for a new claim in a reexamination.

B. The Federal Circuit's Decision Is Inconsistent with Its Own Precedent that an Amended or New Claim Must Be Submitted To Distinguish Prior Art or To Respond to an Adverse Patentability Decision

The Federal Circuit's decision to permit Cordis to submit new claim 44 for a reason other than to distinguish prior art or to respond to an adverse

patentability decision is also inconsistent with its own precedent interpreting section 305.

Prior to its decision in this case, the Federal Circuit had interpreted section 305 to limit a patent owner's ability to submit amended or new claims solely to submission for the purpose of distinguishing the prior art:

> [T]he ability of a patentee to amend claims during reexamination must be seen in light of the fundamental purpose of reexamination – the determination of validity in light of a substantial new question of patentability. Thus, amendment of claims during reexamination is limited to amendment in light of prior art raising a substantial new question of patentability.

In re Freeman, 30 F.3d 1459, 1468 (Fed. Cir. 1994).

In a recent decision issued after its decision (and denial of rehearing) in this case, the Federal Circuit applied *Freeman* and held that a claim amended during reexamination for a purpose other than to distinguish the prior art was invalid for failure to comply with section 305:

> Under 35 U.S.C. § 305, a patent owner may propose an amendment to its patent to distinguish the claimed invention from the prior art or to respond to an adverse decision as to the patentability of one of the claims. Claim amendments during reexamination are

> limited to "amendment in light of prior art raising a substantial new question of patentability." *In re Freeman*, 30 F.3d 1459, 1468 (Fed. Cir. 1994). As in *Freeman*, Collins cannot use reexamination for the purpose of amending its claims to address an adverse claim construction.

Southwestern Bell Tel. Co. v. Arthur A. Collins, Inc., 2008 U.S. App. LEXIS 11274, at *5-6 (Fed. Cir. May 27, 2008) (non-precedential).

The Federal Circuit inexplicably failed to refer to *Freeman* in any way in this case, even though it was the primary precedent cited by BSC on appeal. App. 53a-56a. The Federal Circuit's decision to permit Cordis to submit new claim 44 not to distinguish the prior art or to respond to an adverse patentability decision, but rather solely to cover competitive products and methods, is inconsistent with its decisions in *Freeman* and *Southwestern Bell*. This inconsistency within the Federal Circuit is yet another reason why this Court should grant the petition in order to provide clarity in this area of the law.

III. The Federal Circuit's Decision Unfairly Tilts the Balance in Favor of Patent Owners and Against Legitimate Competitors Who Make Investment Decisions Based on the Public Record of the Original Patent and Its Prosecution

The third reason why the Court should grant the petition is that the Federal Circuit's decision also upsets the balance between patent protection and legitimate

competition. A third party such as BSC should be able to evaluate the scope of a competitor's patent and make investments decisions based on the public record of the original claims, specification, and prosecution history. As this Court stated in *Festo*:

> The patent laws "promote the Progress of Science and useful Arts" by rewarding innovation with a temporary monopoly. U.S. Const., Art. I, § 8, cl. 8. The monopoly is a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not. For this reason, the patent laws require inventors to describe their work in "full, clear, concise and exact terms," 35 U.S.C. § 112, as part of the delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150, 109 S.Ct. 971, 103 L.Ed.2d 118 (1989).

Festo, 535 U.S. at 730-31.[6]

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[6] *See also Markman*, 517 U.S. at 390

("As we noted in *General Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369, 82 L. Ed. 1402,

(Cont'd)

The Federal Circuit's decision undermines these principles because it permits a patent owner to return to the Patent Office many years after a patent has issued and improperly initiate and exploit an *ex parte* reexamination proceeding to broaden the scope of its claims and submit new claims in order to strengthen its position in parallel litigation. By doing so, the decision unfairly tilts the balance in favor of patent owners and against legitimate competitors, who should be entitled to rely on the public record of the original patent and its prosecution in order to make investment decisions, without worrying about the patent owner later returning to the Patent Office to expand the scope of its monopoly.

(Cont'd)

> 58 S. Ct. 899 (1938), 'the limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public.' Otherwise, a 'zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field,' *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236, 87 L. Ed. 232, 63 S. Ct. 165 (1942), and 'the public [would] be deprived of rights supposed to belong to it, without being clearly told what it is that limits these rights.' *Merrill v. Yeomans*, 94 U.S. 568, 573, 24 L. Ed. 235 (1877).").

IV. Granting this Petition Would Permit this Court To Address the *Ex Parte* Reexamination Statute for the First Time Since its Enactment Almost Thirty Years Ago and To Confirm Its Limited Purpose

Finally, the fourth reason why the Court should grant the petition is that this case presents a rare opportunity for this Court to address the *ex parte* reexamination statute for the first time since it was enacted in 1980. Petitioners have not uncovered any decisions from this Court that address this statute. The Court should grant the petition and confirm the limited purpose of reexamination proceedings in order to restore the balance between patent protection and legitimate competition that has been upset by the Federal Circuit in this case.

CONCLUSION

For the foregoing reasons, Petitioners Boston Scientific Corporation and Boston Scientific Scimed, Inc. respectfully request that this Court grant the petition for a writ of certiorari and reverse the judgment of the Federal Circuit that claim 23 is infringed and that claim 44 is not invalid.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED JANUARY 7, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2006-1393, -1394, -1395, -1396, -1415, -1416

CORDIS CORPORATION,

Plaintiff-Cross Appellant,

v.

MEDTRONIC AVE, INC.,

Defendant-Appellant,

and

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Defendants-Appellants.

Appendix A

MEDTRONIC AVE, INC.,

Plaintiff-Appellant,

v.

CORDIS CORPORATION, JOHNSON AND JOHNSON, and EXPANDABLE GRAFTS PARTNERSHIP,

Defendants-Appellees.

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Plaintiffs-Appellants,

v.

ETHICON, INC., CORDIS CORPORATION, and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants-Cross Appellants.

Appeals from the United States District Court for the District of Delaware in consolidated cases 97-CV-550, 97-CV-700, and 98-CV-19, Judge Sue L. Robinson.

DECIDED: January 7, 2008

Appendix A

Before BRYSON, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and, KEELEY, Chief District Judge.*

BRYSON, *Circuit Judge.*

These consolidated appeals arise from two related cases in the United States District Court for the District of Delaware. In both cases, Cordis Corp. alleged that the defendants had infringed its patents covering vascular stents that are used to treat coronary artery disease. After separate trials, Cordis obtained jury verdicts of infringement against defendant Medtronic AVE, Inc., ("AVE") in the first case and co-defendants Boston Scientific and Boston Scientific Scimed, Inc., (collectively, "BSC") in the second case. AVE and BSC each filed a motion for a new trial and for judgment as a matter of law ("JMOL"). They now appeal from the district court's denial of those motions. Cordis has cross-appealed from the district court's invalidation of a claim that the jury found to have been infringed by BSC. We affirm the judgments against AVE and BSC, and on Cordis's cross-appeal we reverse the invalidity ruling.

I

These appeals involve two patents, U.S. Patent No. 4,739,762 ("the '762 patent") and U.S. Patent No. 5,195,984 ("the '984 patent"). The '762 patent discloses

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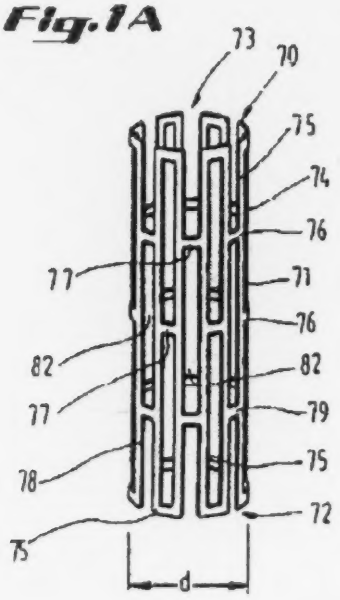
* Honorable Irene M. Keeley, Chief Judge, United States District Court for the Northern District of West Virginia, sitting by designation.

Appendix A

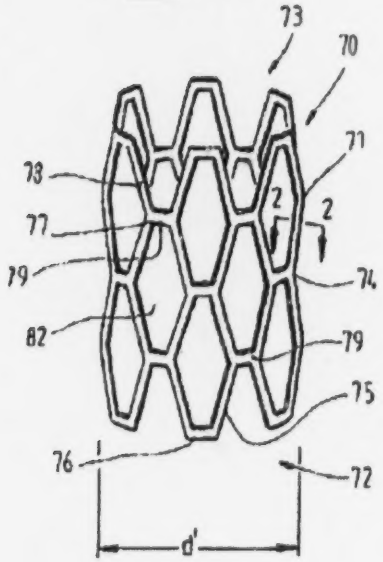
a coronary stent that can be mounted on an angioplasty balloon and delivered to a target location intraluminally (i.e., through the vascular system) by a catheter. Once the stent and balloon reach the desired location, the balloon is inflated to expand the stent to a desired size. At issue in both cases is claim 23 of the '762 patent, which covers an expandable intraluminal vascular stent comprising "a ... tubular member having ... a wall surface ..., the wall surface having a substantially uniform thickness and a plurality of slots formed therein." '762 patent, col. 11, ll. 63-67. Claim 23 further requires the wall surface to be a "smooth surface." *Id.*, col. 12, ll. 57-58. The figures below, taken from the '762 patent, show the disclosed stent in its collapsed (Fig.1A) and expanded (Fig. 1 B) forms.

Fig. 1A



Appendix A

Fig. 18



After the litigation against AVE and BSC was underway, Cordis requested reexamination of the '762 patent in light of a number of prior art references. During reexamination, Cordis narrowed the patent's scope by distinguishing the claimed invention from a prosthetic implant in the form of a tubular sleeve that is disclosed in U.S. Patent No. 3,657,744 to Ersek. Cordis amended its claims by canceling independent claim 13 and incorporating all the limitations of that claim into claim 23, which had previously depended from claim 13. In remarks accompanying the amendment, Cordis distinguished the claimed invention from the

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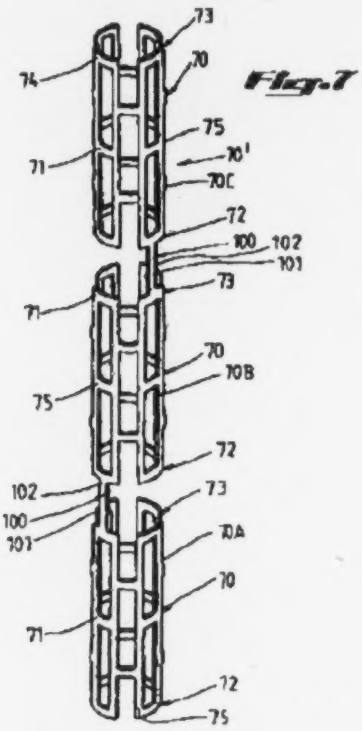
Ersek sleeve based on the "wall surface," "smooth surface," and "substantially uniform thickness" limitations.

The second patent involved in these appeals, the '984 patent, discloses a flexible stent manufactured by joining tubular members, such as those disclosed in the '762 patent, by a connector that "provides the necessary flexibility to negotiate the bends and curves in tortuous body passageways, such as the vascular system." '984 patent, col. 4, ll. 23-25. The disclosed flexible stent is depicted in the figures below taken from the '984 patent.



Appendix A

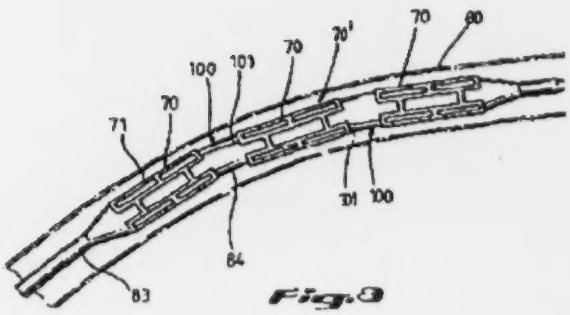
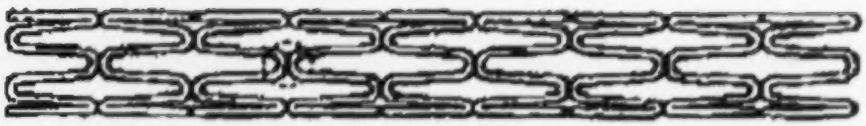


Fig. 3

II

We first address AVE's appeal. Cordis alleged that three of AVE's stents infringe the '762 and '984 patents: the MicroStent II, the GFX, and the GFX 2. Those stents are each made from rounded lengths of stainless steel that are formed into rings. The rings are heated to a temperature sufficient to permit them to be formed, and they are then folded into sinusoidal structures. Each sinusoidal ring has straight portions, which AVE refers to as "struts," and curved portions at the ends of the struts, which AVE refers to as "crowns." To create the complete stent, adjacent sinusoidal rings are welded together at a point between one of the crowns of each ring. The drawing below depicts one of the AVE stents consisting of multiple sinusoidal rings welded together; the dashed circle identifies one of the weld points between two crowns on adjacent rings.

Appendix A



The first trial in the AVE case was held in 2000. Prior to trial, the district court granted partial summary judgment for AVE, holding that its stents did not literally infringe the "plurality of slots formed therein" limitation. After trial, however, the jury returned a verdict in Cordis's favor, finding that AVE's stents infringed the '762 and '984 patents under the doctrine of equivalents. The district court then granted AVE's motion for JMOL of noninfringement under the doctrine of equivalents, holding that Cordis was barred from asserting equivalents for the "plurality of slots formed therein" and "substantially uniform thickness" limitations of claim 23. The district court also entered a conditional order granting a new trial on the issue of whether AVE's stents literally infringe the "substantially uniform thickness" limitation.

On Cordis's appeal, we reversed the district court's construction of the claim terms "plurality of slots formed therein" and "substantially uniform thickness." The district court had construed the "plurality of slots formed therein" to require that the slots be formed by removing material from a preexisting wall surface. We held that the slots were not required to be formed by any

particular process. *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1356-60 (Fed.Cir.2003) ("*Cordis I*"). We also held that the district court had erred in narrowly construing the "substantially uniform thickness" limitation. The district court had held that the prosecution history showed that in the course of distinguishing the Ersek sleeve, Cordis had disclaimed stents varying in thickness "by 0.001 inch or more." *Id.* at 1360. After reviewing the prosecution history, we concluded that Cordis had not clearly and unmistakably disclaimed stents having more than that degree of variation in thickness. *Id.* at 1362. Instead, we construed "substantially uniform thickness" to mean that "the walls must be of largely or approximately uniform thickness." *Id.* at 1360. We added that the prosecution history supported a finding that Cordis disclaimed stents having walls varying in thickness by at least 100 percent. *Id.* at 1362.

On remand, the district court in 2005 held a retrial on whether AVE's stents literally infringed the "substantially uniform thickness" limitation. The jury returned a verdict in Cordis's favor, and the district court denied AVE's motions for JMOL of noninfringement and a new trial. The district court also denied AVE's renewed motion for JMOL of noninfringement with regard to the '984 patent's "flexibly connect" limitation, which the jury in the 2000 trial had found infringed.

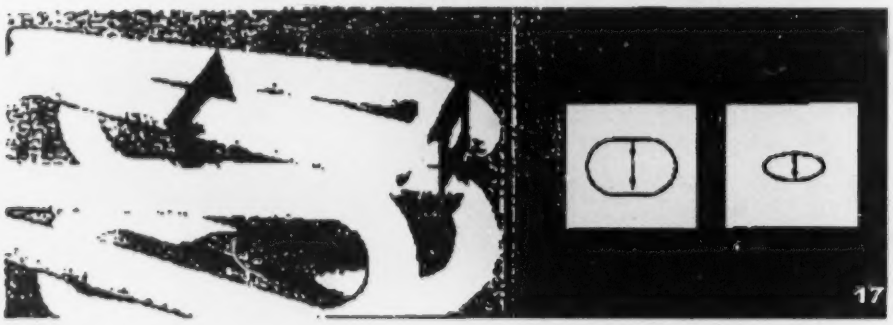
On appeal, AVE argues that it is entitled to JMOL of noninfringement of the '762 patent because its stents

do not have walls with "substantially uniform thickness." It argues that it is entitled to JMOL of noninfringement of the '984 patent because the welds on its stents do not "flexibly connect" the individual sinusoidal rings. In the alternative, AVE argues that it is entitled to a new trial on several grounds.

A

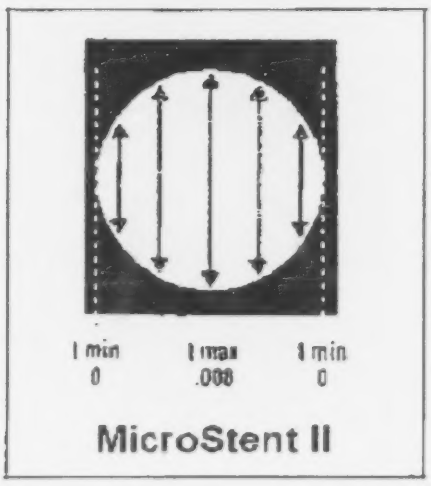
AVE first argues that its stents do not satisfy the "substantially uniform thickness" limitation of claim 23. AVE explains that its stents are made from a group of rings consisting of thin metal strands having circular or ellipto-rectangular cross-sections. Each ring is bent into a sinusoidal shape so that it forms a tube-like member. The tube-like segments are then welded together to form the stent. The sinusoidal segments therefore make up the wall of the stent. As a result of the sinusoidal shape of the stent segments, the walls of the AVE stents consist of a large number of straight sections (struts) with curved sections (crowns) between each pair of straight sections. There is a sharp curve at the tip of each crown where the metal strand curves back to form another strut, as shown in the figure above that represents an AVE stent. AVE acknowledges that in the strut areas the thickness of the stent wall is measured by the cross-sectional diameter of the metal strands and that because the thin metal strands from which the stents are made are uniform in cross-section, the wall thickness of the AVE stents in the strut areas is uniform. In the crown area, however, AVE contends that the thickness of the stent wall should be measured not by

the cross-sectional diameter of the thin metal strands that make up the stent wall, but by the length of the chords that cross the curved tip of the crown, as measured along a line drawn from the center of the stent perpendicular to the wall. Because of the curvature of the crown tips, those chords become increasingly short as the point of measurement approaches the tip of the crown. Based on that proposed method of measurement, AVE contends that the thickness of the wall surface of its stents decreases to zero at the very tip of each crown and thus the wall thickness of each of its stents varies by 100 percent. The image below displays two measurements of thickness according to AVE's method of measurement. The left-hand box shows AVE's method of measuring the thickness of the stent wall in the strut area and at the crown. In the right-hand box, the first figure corresponds to the diameter of the stent as measured in the middle of the strut, while the second figure corresponds to the shorter chord across the crown of the stent, as measured at the tip of the crown.

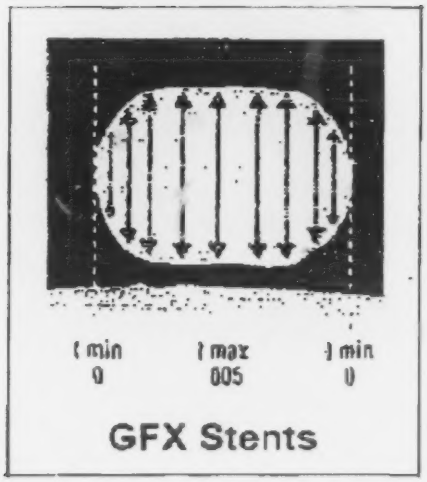


Appendix A

AVE's argument about wall thickness is only a slightly modified version of its argument in the prior appeal. In that appeal, AVE argued that because the struts that make up the stent are round, the wall does not have uniform thickness. We rejected that argument because, "according to the patents' claims, it is the wall surface that needs to have a uniform thickness, and the full circumference of the round strut is not involved in making up the wall surface." *Cordis I*, 339 F.3d at 1362. We explained that experts from both sides agreed that "persons of ordinary skill in the art equate thickness with diameter in the case of round struts." *Id.* We thus rejected AVE's argument that the thickness of the wall surface must be measured by each of the shorter chords that cut across the round or ellipto-rectangular cross-section of the strut, as depicted in the figures below.



Appendix A



AVE now argues that its stents do not meet the "substantially uniform thickness" limitation as a matter of law, because the thickness of the wall diminishes in the tapered end of the crown. That argument, however, like the argument we rejected in the last appeal, is based on the notion that a cylindrical metal strand produces a wall thickness that varies according to the length of the particular chord across the cylinder that is chosen for measurement. In the prior appeal, we rejected AVE's argument as applied to the struts, holding that "a stent with round struts can have a substantially uniform thickness as long as the round struts have substantially the same diameter." *Cordis I*, 339 F.3d at 1362. In this appeal, we reject AVE's argument as applied to the

crowns, holding that a stent with round crowns can have substantially uniform thickness as long as the round crowns have substantially the same diameter.

AVE argues that a portion of our discussion of the wall thickness issue in the prior appeal requires a different result. In *Cordis I*, in an effort to illustrate the point that wall thickness is represented by the diameter of the struts, we characterized the diameter of the round strut as equal to the distance between the outer point of the strut that intersects an imaginary circle that constitutes the outer wall of the stent and the corresponding inner point that intersects a similar imaginary circle on the inside of the tubular member. 339 F.3d at 1362. Both at the 2005 trial and now on appeal, AVE has contended that our reference to "imaginary circles" justified, and indeed compelled, the court and the jury to conclude that the walls of its stents are not uniform in thickness. AVE's argument is predicated on the view that at the tip of each crown in the AVE stents, the inner imaginary circle would become larger and the outer imaginary circle would become smaller until the two met at the very tip of the crown, where the stent wall would have a thickness of zero.

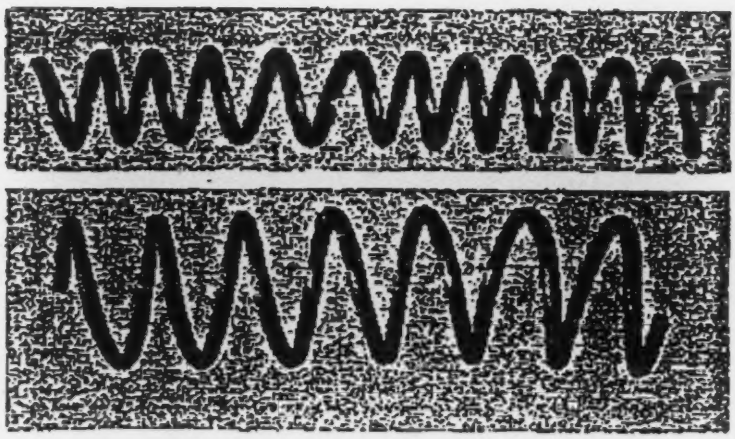
Pursuant to its "imaginary circles" theory of wall thickness, AVE requested at the 2005 trial that the court instruct the jury that it should measure wall thickness using the following methodology:

> To determine whether the "substantially uniform thickness" limitation of all the

> asserted claims is satisfied, the thickness of the wall at each point along the stent is measured by looking at two imaginary circles, one on the outside, touching the outermost points of the circle, and one on the inside, touching the innermost points of the circle, and measuring the distance between these two circles. The thickness of the wall of the stent must be largely or approximately uniform along its length and between members. A wall that varies in thickness by as much as 100 percent is not largely or approximately uniform and thus does not have a substantially uniform thickness.

The district court rejected that requested instruction, and properly so. AVE sought to adopt the "imaginary circles" method of measuring thickness from our prior opinion in *Cordis I,* but without reference to the context in which that method was discussed. In *Cordis I,* we referred to the imaginary circles to illustrate the concept that wall thickness, in the case of a wall made up of a thin metal strand having a round cross-section, should be measured by the diameter of the metal strand, not by some portion of the metal strand other than its diameter. AVE's use of imaginary circles would have exactly the opposite effect—it would result in the thickness of the stent wall being measured by reference to some portion of the metal strand other than its diameter. The trial court properly declined to give an instruction that would so clearly contravene the entire point of the analysis we employed in *Cordis I.*

Appendix A



Not only does AVE's interpretation of the phrase "substantially uniform thickness" conflict with our prior opinion in this case, but it conflicts with AVE's own explanation of the prior art. In its brief, AVE refers to two articles by Dr. Charles Dotter that discuss expandable stents consisting of cylindrical wire twisted into coils. AVE describes those stents, which are depicted here, as having "uniform wall thickness." That description is consistent with our conclusion in the prior appeal that "a stent formed from struts with circular or ellipto-rectangular cross-sections can have a wall of substantially uniform thickness." *Cordis I*, 339 F.3d at 1362. Yet there is no reason that the wall thickness of AVE's stents, which consist of sinusoidal curves disposed in a cylindrical plane, should be viewed any differently than the wall thickness of the stents disclosed by Dotter, which consist of coils disposed in a cylindrical plane. Put another way, the wall thickness in one of Dotter's stents

would not cease to be uniform if the cylindrical wire making up the coil were bent into a sinusoidal shape from place to place along the surface of the coil. For that reason as well, it was proper for the district court to decline to instruct the jury in accordance with AVE's request.

AVE also argues that it was error for the trial court to leave to the jury the issue of how to measure the thickness of the stent wall. According to AVE, the methodology of measurement should have been deemed an issue of law for the court rather than an issue of fact that was part of the infringement inquiry submitted to the jury. Even if the issue of the proper methodology for measurement should have been treated as a pure question of law, however, we reject AVE's argument that the trial court should have adopted AVE's methodology in determining how the wall thickness should be measured. Therefore, the trial court's treatment of the methodology issue as a question of fact could not have prejudiced AVE, as it gave AVE an opportunity to present its theory to the jury, even though the court would have been justified in refusing to permit AVE to introduce evidence regarding its theory as to how to measure wall thickness.

Although AVE took advantage of the opportunity it was given to present its evidence to the jury as to the proper method for measuring wall thickness, the jury ruled against AVE on that issue, and the jury's verdict was supported by substantial evidence. At trial, Cordis's engineering expert, Dr. Collins, testified that an

engineer would "measure the thickness of the cross-section of the structural element" and that "the strut is the structural element." That is, even though the stent wall curves in the crown area, an engineer would nevertheless determine the thickness of the stent wall by measuring the thickness of the struts, which are uniformly thick. Dr. Collins stated that the rounding of the edges would not affect his analysis. AVE's expert, Dr. Wagoner, presented conflicting testimony, stating that an engineer would measure the thickness of a stent's wall by comparing the inner diameter of the stent to the outer diameter. Under Dr. Wagoner's approach, the thickness measurement would taper near the ends of each of AVE's stents, leading to his conclusion that the stents do not have uniform thickness along two percent of their length. Dr. Collins's testimony, however, is not only consistent with the approach taken to the "wall thickness" issue in our prior opinion, but constitutes substantial evidence of infringement if the mode of measuring wall thickness is treated as part of the factual component of the infringement inquiry.

B

AVE next argues that it is entitled to JMOL of noninfringement of the '984 patent because its stents do not infringe the "flexibly connect" limitation of the asserted claims of that patent. In the 2000 trial, the jury found that AVE's stents infringed claims 1 and 3 of the '984 patent, which cover vascular grafts having a "plurality of thin-walled tubular members" with connector members "to flexibly connect adjacent tubular

members." '984 patent, col. 11, ll. 53-55. Construing that limitation, the district court stated that "to flexibly connect adjacent tubular members means to connect in such a way as to allow turning, bowing or twisting without breaking. The connector member must provide flexibility, whether or not the adjacent tubular members themselves are flexible." In its motion for JMOL of noninfringement after the 2000 trial, AVE argued that its stents do not infringe because their connector members are not flexible. That issue was not part of the prior appeal, and after the 2005 trial, AVE raised it in a renewed motion for JMOL, which the district court denied.

As an initial matter, AVE reads the claim language and the district court's claim construction to require the connector members themselves to be flexible, rather than simply providing flexibility to the device as a whole. As a result, in arguing that its stents do not meet the "flexibly connect" limitation, AVE relies on statements from Cordis's experts to the effect that the welds in and of themselves are not flexible. Neither the claim language nor the district court's claim construction, however, requires the connector members to be flexible. Rather, the claim language requires the connector members to "flexibly connect adjacent tubular members," and the district court construed that phrase to require the connector members to "provide flexibility." Even if the connector members themselves are not flexible, Cordis's evidence was sufficient to demonstrate that the connector members nevertheless provide flexibility to AVE's accused stents.

Appendix A

At the 2000 trial, one of Cordis's experts, Dr. Stringfellow, testified regarding a finite element analysis he performed to simulate bending in AVE's stents. Finite element analysis is a computer simulation technique used to model the real-world behavior of physical structures. Based on his simulation, Dr. Stringfellow estimated that the connectors, as used in AVE's GFX stent, account for about 22 percent of the stent's bending, while only making up five percent of the stent's length. AVE contends that Dr. Stringfellow's testimony should be disregarded. It argues that Dr. Stringfellow was not qualified to perform the finite element analysis because he had never designed a stent and was not familiar with the forces a stent would experience during delivery. AVE also argues that Dr. Stringfellow used incorrect assumptions and data in his simulation. The record, however, shows that Dr. Stringfellow had a doctoral degree in mechanical engineering and extensive experience performing finite element analyses. The trial court acted well within its discretion in holding that he was qualified to testify under Federal Rule of Evidence 702. As for AVE's concerns about the assumptions and data that Dr. Stringfellow used in his analysis, AVE was free to, and did, present those concerns to the jury. Notwithstanding AVE's criticism of Dr. Stringfellow's methodology, the jury was entitled to credit Dr. Stringfellow's testimony, and based on that testimony it was reasonable for the jury to conclude that AVE's stents have connector members that satisfy the "flexibly connect" limitation, even if the connector members themselves are not flexible.

Appendix A

C

AVE contends that it is entitled to a new trial on several grounds. First, AVE challenges the district court's decision to prevent AVE and its experts from telling the jury that AVE's method of measuring stent wall thickness was endorsed by our opinion in the prior appeal in this case. As explained above, the portion of the opinion on which AVE relies dealt with whether "a stent formed from struts with circular or ellipto-rectangular cross-sections can have a wall of substantially uniform thickness." *Cordis I*, 339 F.3d at 1362. In explaining why we concluded that a jury could reasonably conclude that such a stent could have a wall of substantially uniform thickness, we described the use of "imaginary circles" as an illustration for how a jury could reach that conclusion. Contrary to AVE's contention, however, that portion of the opinion did not reflect this court's agreement with AVE's theory as to how to measure the thickness of the stent wall. Moreover, it was for the court, not the jury, to interpret this court's prior opinion. The district court therefore properly barred AVE and its experts from telling the jury that our prior opinion supported AVE's theory as to the proper manner to measure the thickness of the walls of AVE's stents.

AVE next argues that it was prejudiced by statements from Cordis's counsel criticizing AVE's method of measuring thickness. During closing argument, Cordis's counsel referred to AVE's method of measurement as "an utterly misleading analysis,"

"a big trick," and "intellectually dishonest," and argued that AVE was "misusing the concentric circles." AVE argues that those statements were prejudicially misleading because they gave the impression that AVE's method "was made up out of whole cloth and had no basis in law or fact." Those comments, however, were all made in the context of arguments for why Cordis's method provided a more rational approach to determining thickness, and its arguments were rooted in evidence on the record. Taken in context, Cordis's comments did not "run the risk of infecting the entire trial," and it is highly unlikely that they improperly influenced the jury. *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1261 (Fed.Cir.2004) (new trial not warranted where Chiron pointed to "no evidence of jury prejudice as a result of the identified statements, which were buried in a seventy-seven page transcript of Genentech's closing argument").

AVE next argues that it was prejudiced by statements from Cordis's counsel during closing argument regarding the method of measuring wall thickness. Counsel argued that AVE's method of measurement would not result in a 100 percent deviation in thickness because "you can't have a negative hundred percent deviation or variation." Counsel's point was that a 100 percent deviation in wall thickness in the crown area would be mathematically impossible because at the tip of the crown, where the level of variation in thickness would reach 100 percent, the stent ends, and therefore any measurement taken at that point or beyond could no longer be considered a measurement of the thickness

of the stent wall. The statement by Cordis's counsel was based on the following testimony by Dr. Wagoner during cross-examination:

> Q: [Y]ou will agree with me that as a mathematical matter there cannot be a hundred percent negative deviation?
>
> A: Deviation, a hundred percent deviation?
>
> Q: Yes.
>
> A: That's a different question. I agree with that.

While the comments of Cordis's counsel can be read to suggest that no reduction in thickness, no matter how great, could exceed the maximum 100 percent variation permitted by the "wall thickness" limitation as construed, counsel's statements taken in context appear principally directed to underscoring the disagreement between Cordis and AVE over the proper way to determine whether a stent meets the "substantially uniform thickness" limitation. It is highly unlikely that the argument made by Cordis's counsel had such a prejudicial effect as to deny AVE a fair trial.

AVE also objects to an argument in which Cordis's counsel told the jury that "you can't have a stent that goes up a hundred percent." AVE misunderstands the point Cordis's counsel was making. The context of the remark makes it clear that counsel was not saying it

was impossible to have a stent with a 100 percent variation in thickness, but instead was saying that a stent could not have a wall surface that varied by more than 100 percent and still fall within the reach of the '762 patent. AVE is not entitled to a new trial as a result of those statements.

Next, AVE argues that it was prejudiced by the district court's exclusion of evidence demonstrating the clinical advantages of the tapered crowns on AVE's stents. AVE sought to have a medical expert testify that the tapered crowns provide for "improved treatment of calcified and tortuous lesions; improved trackability and conformability; and improved side branch access." AVE's argument that it was prejudiced by the exclusion of that evidence is without merit. First, that evidence is irrelevant to the question of infringement. The jury was asked to determine whether AVE's stents infringe the '762 patent, not whether the stents perform better than the '762 patent's preferred embodiment. Second, despite the irrelevance of the clinical benefits of the tapered crown, AVE nevertheless was permitted to introduce such evidence from other sources. For instance, a senior engineer from AVE testified that the tapered crowns "minimize[ ] resistance in the vessel . . . and disruption of the vessel."

Finally, AVE challenges the court's instruction to the jury on obviousness, arguing that it conflicts with the Supreme Court's recent decision in *KSR Int'l Co. v. Teleflex Inc.*, __ U.S. __, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007). AVE points to two sentences of the

obviousness instruction as contrary to *KSR*. In those two sentences, the court told the jury, "If the prior art references as a whole do not teach, suggest or motivate that combination, then they may not be combined. The mere fact that the prior art can be modified does not make the modification obvious unless the prior art suggests the desirability of the modification." In the preceding sentence of the instruction, the court stated, "A suggestion to combine references may also flow from the nature of the problem or from the ordinary knowledge of those skilled in the art that certain references are of special importance."

AVE has not demonstrated that the jury instruction, when read in its entirety, conflicts with the Supreme Court's holding that the teaching-suggestion-motivation test should not be applied rigidly. Moreover, not only did AVE not object to the instruction that it now challenges, AVE actually proposed that instruction. The instruction therefore either constitutes "invited error" that is not reviewable at all, or at most is subject to review under the "plain error" standard. *See Maxwell Land-Grant Co. v. Dawson*, 151 U.S. 586, 606, 14 S.Ct. 458, 38 L.Ed. 279 (1894); *Herman v. Hess Oil Virgin Islands Corp.*, 524 F.2d 767, 772 (3d Cir.1975). Under Third Circuit law, to which we look for the standard to apply in reviewing claimed instructional errors from a district court in that circuit, AVE must show, at a minimum, that any error in the obviousness instruction was "fundamental and highly prejudicial" or that "the instructions are such that the jury [was] without adequate guidance on a fundamental question and our

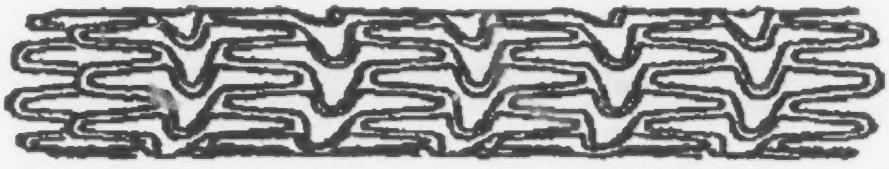
failure to consider the error would result in a miscarriage of justice." *Bostic v. Smyrna Sch. Dist.*, 418 F.3d 355, 359 (3d Cir.2005) (internal quotations omitted).

AVE argues that it should not be penalized for requesting an instruction based on the state of the law before *KSR*, because in its view *KSR* resulted in a significant change in the law. The Supreme Court, however, stated that "[t]here is no necessary inconsistency between the idea underlying the TSM test and the *Graham* [*v. John Deere Co.*, 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966)] analysis." *KSR*, 127 S.Ct. at 1741. This court's error, the Supreme Court explained, was to "transform[ ] the general principle into a rigid rule that limit[ed] the obviousness inquiry." *Id.*; *see also Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed.Cir.2007) ("As long as the [TSM] test is not applied as a 'rigid and mandatory' formula, that test can provide 'helpful insight' to an obviousness inquiry." (quoting *KSR*, 127 S.Ct. at 1731)). In any event, even in the case of a change in the law, the Supreme Court has held that the plain error standard applies to a jury instruction to which no objection was made. *See Johnson v. United States*, 520 U.S. 461, 465-66, 117 S.Ct. 1544, 137 L.Ed.2d 718 (1997). Under that standard, AVE has not remotely demonstrated that it is entitled to a new trial on obviousness.

Appendix A

III

We turn next to BSC's appeal. Cordis asserts that a BSC stent called the NIR stent infringes claim 23 of the '762 patent. The NIR stent is manufactured from a stainless steel sheet. Slots are formed in the steel sheet by chemical etching. Unlike the stent disclosed in the '762 patent, the slots in the NIR stent are not rectangular. Instead, they are rounded at the ends, and each slot contains a U-shaped curve in the middle. The U-shaped portions protrude slightly when the stent is in its collapsed form. BSC refers to the U-shaped portions along the stent's surface as "U-loops." BSC's central argument is that those U-loops prevent the NIR stent from infringing claim 23.



At the 2000 trial the jury returned a verdict against BSC, finding that BSC infringed claim 23 under the doctrine of equivalents. The district court, however, granted BSC's motion for a new trial, holding that it should have instructed the jury regarding prosecution history estoppel for the "substantially uniform thickness" limitation. The district court stayed the new trial pending the outcome of Cordis's appeal in the AVE

case, in which we found that "substantially uniform thickness" means that "the walls must be of largely or approximately uniform thickness" with variations of thickness of at least 100 percent disclaimed. *Cordis I*, 339 F.3d at 1360, 1362.

On remand, the district court amended its claim construction to be consistent with this court's construction in *Cordis I*, 339 F.3d at 1360-62, and *Cordis Corp. v. Boston Scientific Corp.*, 99 Fed.Appx. 928, 932-33 (Fed.Cir.2004). The court construed the phrase "substantially uniform thickness" to mean that walls "must be of largely or approximately uniform thickness." The court then held a new trial, at the conclusion of which the jury once again returned a verdict of infringement. The district court denied BSC's ensuing motions for JMOL and a new trial.

BSC appeals from the verdicts in both the 2000 trial and the 2005 retrial. From the 2000 trial, BSC appeals the denial of its motions for JMOL and a new trial, arguing that the district court relied on an erroneous construction of the term "slots." In addition, BSC challenges the 2000 jury's verdict on the "wall surface" and "smooth surface" limitations. At the 2005 retrial, in which the issue of infringement was restricted to the "substantially uniform thickness" limitation, the jury returned a verdict of literal infringement. BSC appeals on several grounds from the denial of its post-verdict motions following that verdict. In addition, BSC appeals from the denial of a new trial on the issue of obviousness, which was litigated in the 2005 trial.

Appendix A

A

BSC first challenges the district court's construction of the term "slots" in the 2000 trial. Claim 23 covers stents with a wall surface having "a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member." '762 patent, col. 11, l. 67 through col. 12, l. 2. The district court construed "slots" to refer to both "complete" slots (slots that are bounded on all sides) and "half" slots (slots that are not completely bounded). That construction allowed Cordis to press its theory that sections of the NIR stent falling between successive U-loops each meet the "tubular member" limitation because, viewed in that manner, the "tubular members" of the NIR stent would not have any complete slots. To support its argument that "slots" should be read to cover only complete slots, BSC relies on a passage from the specification that distinguishes half slots from complete slots:

> Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71.

'762 patent, col. 7, ll. 7-13. The initial reference to "alternating slots" refers to the half-slots at the end of the tubular member. Although the written description

adopts a more specific term for those slots ("half-slots"), that does not foreclose the generic term "slots" from being used to refer to both half slots and complete slots. The written description uses the more specific phrase "complete slots" when distinguishing complete slots from half slots, and thus supports the inference that the term "slots," as used in claim 23, refers to both complete slots and half slots. If the patentee had intended claim 23 to only cover grafts with tubular members having complete slots, the patentee presumably would have drafted the claim to specify "complete slots," the term used in the written description to describe such fully bounded slots.

BSC also argues that the district court's construction of "slots" cannot be correct because, under that construction, the claim would cover inoperable embodiments. For that argument, BSC relies on *Frank's Casing Crew & Rental Tools v. Weatherford International, Inc.*, 389 F.3d 1370, 1378 (Fed.Cir.2004), in which this court construed a means-plus-function limitation in a manner that avoided "render[ing] the patent internally inconsistent and the invention inoperable." *Frank's Casing Crew* does not provide the support for BSC's argument because means-plus-function claims by their very nature must be read to avoid rendering the invention inoperable. To be sure, even outside the means-plus-function context, we have stated that "a construction that renders the claimed invention inoperable should be viewed with extreme skepticism." *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371, 1376 (Fed.Cir.), *vacated and*

remanded on other grounds, 537 U.S. 802, 123 S.Ct. 70, 154 L.Ed.2d 3 (2002). But that statement refers to a construction that would render all embodiments of a claimed invention inoperable, not a construction that might cover some inoperable embodiments. *See EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1349 (Fed.Cir.2001) ("the party alleging inoperability must show that each disclosed embodiment in the patents was impossible or not enabled.").

In any event, the district court's construction of the term "graft" in claim 23 prevents the claim from covering inoperable stents. As BSC points out, the district court's construction of "graft" states that "[a] graft ... must be functional, that is, once it is expanded and deformed it must be capable of serving to prevent a body passageway from collapsing." Therefore, a graft, or stent, would not infringe claim 23 if it consisted of only a single tubular member that would not be long enough to prevent a vessel from collapsing. Claim 23, however, recites a graft *comprising* a tubular member, not a graft *consisting of* a single tubular member. *See Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1327-28 (Fed.Cir.1999) (" 'comprising' is inclusive . . . or open-ended and does not exclude additional, unrecited elements or method steps," quoting Patent and Trademark Office, Department of Commerce, *Manual of Patent Examining Procedure*, § 2111.03 (6th ed. 1997) ("MPEP")). Thus, the claim is not precluded from covering grafts that are constructed by linking multiple tubular members, any one of which, by itself, might not be capable of preventing vessel collapse.

BSC also contends that the district court's construction of the term "slots" is incorrect because a stent having only half slots could not satisfy the "tubular member" limitation, which the district court construed to mean "elongated" (i.e., "having a form notably long in comparison to its width"). BSC's argument, however, assumes that half slots must have a fixed size that would prevent a half-slotted tubular member from being elongated. The district court's construction of "slots" does not require BSC's assumption to be true. Whether the tubular members of the NIR stent, as identified by Cordis, meet the "tubular member" definition is a separate question of infringement that does not affect the correctness of the district court's construction of "slots." BSC has not challenged the jury's finding that the "tubular member" identified by Cordis is elongated.

B

BSC argues that the jury's verdict in the 2000 trial that the NIR stent infringes claim 23 must be overturned because no reasonable jury could find that the NIR stent literally infringes the "wall surface" and "smooth surface" limitations, and because prosecution history estoppel bars the availability of equivalents for those limitations. The trial court defined the "wall surface" limitation to require that the "outer surface of the tubular member must be disposed in a common cylindrical plane"; the court defined the "smooth surface" limitation to require that the "outside of the wall surface of the unexpanded tubular member [have] a continuously even surface, without roughness, points,

bumps or ridges, especially to the touch." The jury returned a general verdict of infringement under the doctrine of equivalents. Based on its analysis of the prosecution history, BSC argues that argument-based estoppel bars the availability of equivalents for both the "wall surface" and "smooth surface" limitations and that amendment-based estoppel bars the availability of equivalents for the "smooth surface" limitation.

1

As to the "wall surface" limitation, we hold that substantial evidence supports a finding of literal infringement and that the trial court therefore properly denied BSC's motion for JMOL on that issue. Because the district court correctly construed the term "slots," the jury was free to accept Cordis's theory that "tubular member" reads on the portion of the NIR stent lying between the stent's U-loops. Therefore, the U-loops do not prevent the tubular member from literally infringing the "wall surface" limitation. The only remaining question is whether, as BSC contends, the weld spots along the stent prevent the "wall surface" limitation from being literally infringed.

The weld spots to which BSC refers are formed as a result of the NIR stent's manufacturing process. After the stent's slot design is etched in a flat sheet of metal, the sheet is rolled into a tube and the ends of the sheet are welded together. That process forms a series of protruding weld spots along a seam of the stent. BSC argues that, with those weld spots, the NIR stent cannot

meet the "wall surface" limitation, which the district court construed as requiring the outer surface of the tubular member to be "disposed in a common cylindrical plane." In pressing that argument, BSC reads the "wall surface" limitation narrowly to require the outer surface to define a perfect cylinder. The district court's construction, however, does not require a perfect cylinder, which of course is an abstraction that cannot be achieved by any real-world device. Accordingly, even without applying the doctrine of equivalents, a jury could find that the outer surface of the NIR stent's tubular member infringes the wall surface limitation because the weld spots only insignificantly affect the shape of the wall surface. Each tubular section has only one weld spot, and Cordis introduced evidence that the weld spots do not rise significantly above the wall surface of the NIR stent and, taken together, make up only about one percent of the total area of the stent's metal outer surface. Thus, a jury could reasonably conclude that the presence of weld spots on the stent's surface does not sufficiently alter the cylindrical character of the outer surface to preclude a finding of literal infringement.

BSC argues in the alternative that it is entitled to a new trial on infringement because the district court should have ruled that prosecution history estoppel bars equivalents of the "wall surface" limitation. Even though we have held that substantial evidence supports a finding that the "wall surface" limitation was literally infringed, the jury returned a general verdict of infringement under the doctrine of equivalents. It is

therefore possible that the jury found the "wall surface" limitation infringed under the doctrine of equivalents. If BSC's argument regarding prosecution history estoppel is correct, the jury's verdict would therefore be tainted. *See Litton Sys., Inc. v. Honeywell Inc.*, 140 F.3d 1449, 1465 (Fed.Cir.1998). For that reason, it is necessary to examine whether the court should have instructed the jury that equivalents were not available for the "wall surface" limitation, as BSC contends. After close review of the prosecution history, we reject BSC's argument and agree with the district court that prosecution history estoppel does not bar application of the doctrine of equivalents with respect to the "wall surface" limitation.

On reexamination, Cordis responded to the examiner's rejection of the claims in the original '762 patent based on the Ersek sleeve. Addressing the claim term "wall surface," Cordis described Ersek as follows:

> The wall of the Ersek sleeve, to the extent that it exists, is comprised of twisted, inclined strands, which present inwardly and outwardly projecting edges and bridge portions that extend radially outwardly of the sleeve. This configuration does not provide "a surface" that is "disposed between the first and second ends" of a tubular member as is recited in claims 13 and 24.

Cordis then described the claimed invention as follows:

> As is evident from the specification of the '762 patent, with particular reference to Figure 1A, the connecting members and elongate members that collectively form the tubular member 71 have an outer surface that is disposed in a common cylindrical plane. No comparable wall surface is present in Ersek's fixation sleeve, and it would render Ersek inoperable for its intended purposes to modify sleeve 16 and eliminate the outwardly projecting edges, since the thus modified sleeve would eliminate the very structure contemplated by Ersek for retaining the associated graft or heart valve within the body passageway.

BSC argues that because the district court referred to the prosecution history to define "wall surface," it should have instructed the jury that prosecution history estoppel limits the range of equivalents available under the doctrine of equivalents. For that argument BSC relies on *Omega Engineering, Inc. v. Raytek Corp.*, 334 F.3d 1314 (Fed.Cir.2003), in which we described the relationship between prosecution disclaimer (limiting claim scope because of statements made by the patentee in prosecution) and argument-based prosecution history estoppel (limiting the scope of the doctrine of equivalents because of statements made by the patentee in prosecution). We explained that "for prosecution disclaimer to attach our precedent requires that alleged

disavowing actions or statements made during prosecution be both clear and unmistakable." *Id.* at 1325-26. We noted that the same standard applies to the doctrine of argument-based estoppel. *Id.* at 1326 n. 1; *see Cordis I*, 339 F.3d at 1363. Relying on that statement, BSC argues that the district court should have held Cordis barred by argument-based estoppel from relying on the doctrine of equivalents with respect to the "wall surface" limitation because of Cordis's statements about that limitation in the prosecution history. The district court, however, correctly rejected that argument.

As BSC points out, an applicant can make a binding disavowal of claim scope in the course of prosecuting the patent, through arguments made to distinguish prior art references. Such argument-based disavowals will be found, however, only if they constitute clear and unmistakable surrenders of subject matter. *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1364 (Fed.Cir.2006); *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1376 (Fed.Cir.1999); *Litton Sys., Inc.*, 140 F.3d at 1458. Moreover, the scope of such a disavowal will depend on the nature of the argument made by the patentee. As the court explained in *Omega*, 334 F.3d at 1324, even in the case of an unequivocal disavowal of claim scope, the court must construe the claim "congruent with the scope of the surrender." In order to constitute binding surrenders of claim scope, the statements in question must be such that "a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1457

(Fed.Cir.1998) (en banc). If the court finds that the patentee made a clear disavowal of the subject matter that is subsequently asserted to be equivalent to the limitation in question, it will preclude the patentee from asserting equivalency as to that subject matter. *See Bayer AG v. Elan Pharm. Res. Corp.*, 212 F.3d 1241, 1252 (Fed.Cir.2000).

In this case, as the district court found, Cordis made no such broad disclaimer of claim scope when it characterized the "wall surface" limitation in the course of the reexamination proceedings. Rather, Cordis simply made explicit the meaning of the term "wall surface" that was already implicit in the patent. When stating that the wall surface of the '762 graft was disposed in a common cylindrical plane, Cordis explained that that characterization was "evident from the specification," including Figure 1A (reproduced above), which shows the stent in its unexpanded state. The "common cylindrical plane" characterization of the wall surface was also consistent with the reference in the specification to the tubular member as having a "first predetermined, collapsed diameter d." '762 patent, col. 9, ll. 28-29. A tubular member with a predetermined diameter is a cylinder. The reference to the "common cylindrical plane" in the prosecution history therefore did not disclaim any subject matter that was otherwise within the scope of the claim language, but merely explained, in more explicit terms, what the claims already covered. In this regard, the prosecution history simply served the purpose of "inform[ing] the meaning of the claim language by demonstrating how the inventor

understood the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed.Cir.2005) (en banc). For that reason, there is no reason to treat Cordis's definitional explanation in the prosecution history as having the effect of surrendering all equivalents that would otherwise have been available under the patent. Because the district court did not find that Cordis's definition of the term "wall surface" constituted a clear and unmistakable disavowal of claim scope that would eliminate any equivalents of the "wall surface" limitation, the district court properly declined to apply the doctrine of argument-based prosecution history estoppel to preclude all equivalents with regard to the "wall surface" limitation.

Cordis's only clear and unequivocal disclaimer as to the "wall surface" limitation was with respect to the wall structure of the Ersek sleeve, which Cordis made clear did not fall within the scope of its definition of "wall surface." In arguing that the Ersek sleeve does not satisfy the "wall surface" limitation, Cordis pointed to the relative thickness of the Ersek sleeve at the "bridge or bond areas" of the sleeve surface and "outwardly projecting edges" of the Ersek sleeve that are "the very structure contemplated by Ersek for retaining the associated graft or heart valve within the body passageway." For that reason, Cordis noted, the Ersek sleeve has "[n]o comparable wall surface" to one "disposed in a common cylindrical plane." That passage makes clear that Cordis disavowed only those devices, such as the Ersek sleeve, that have a wall surface not "comparable to" the wall surface of the disclosed stent.

That statement clearly disavows a wall surface such as that in the Ersek sleeve, but it does not disavow any equivalents to the wall surface "disposed in a common cylindrical plane." *See Conoco, Inc.*, 460 F.3d at 1364 (argument-based surrender of a particular possible equivalent is not "a clear surrender of other possible equivalents"); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 939 F.2d 1540, 1544 (Fed.Cir.1991) (argument distinguishing a prior art device did not "curtail the scope of equivalents in such a manner as to preclude a finding that [the accused device infringes] under the doctrine of equivalents"). Thus, the prosecution history leaves room for the jury to determine whether the NIR stent has a wall surface comparable to the stent disclosed in the '762 patent that would infringe either literally or under the doctrine of equivalents.

2

As to the "smooth surface" limitation, we hold that the district court properly sustained the verdict of infringement, although we do so on a different ground than that employed by the district court. Because we agree that the jury's verdict is well supported, we uphold the district court's rulings denying BSC's motions for JMOL and a new trial.

The district court held that the evidence at trial supported a finding of literal infringement of the "smooth surface" limitation because substantial evidence supported the jury's finding that the NIR stent had a smooth surface, i.e., what the court defined

as a "continuously even surface, without roughness, points, bumps or ridges, especially to the touch." With respect to infringement under the doctrine of equivalents, the court concluded that the evidence would have supported a verdict in Cordis's favor on that theory as well. Moreover, the court held that amendment-based prosecution history estoppel did not apply, because Cordis managed to rebut the presumption of surrender that was created by the amendment to claim 23 on reexamination. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002). On our view of the case, we find it unnecessary to decide whether the district court was correct to hold that Cordis successfully rebutted the *Festo* presumption with respect to the "smooth surface" limitation. That is because the definition of "smooth" that Cordis set forth in the prosecution history was sufficiently broad that it necessarily encompassed the NIR stent. Although the district court gave the jury a narrower definition at trial, Cordis has argued on appeal that the instruction actually given by the district court was unnecessarily restrictive, and we agree. Under the correct instruction, a reasonable jury would necessarily have found that the NIR stent infringed the "smooth surface" limitation. As such, it is not necessary to look to the doctrine of equivalents as the basis for upholding the jury's verdict on that issue.

As discussed above, Cordis incorporated the "smooth surface" limitation from claim 23 into the independent claims of the '762 patent on reexamination

in order to distinguish the Ersek device, which Cordis described as having a rough outer surface that prevented intraluminal delivery. In distinguishing the fixation sleeve disclosed in the Ersek patent, Cordis stated:

> The inner and outer surfaces of the Ersek sleeve 16 are not smooth, as that term is understood by persons of skill in the art (Andros Declaration, paragraphs 18 and 21.) See also dictionary definitions of smooth—"having an even or level surface; having no roughness or projections that can be seen or felt", and rough—"not smooth or level; having bumps, projections, etc." (Exhibit 2 hereto) from which it is clear that such terms are commonly understood antonyms, and mutually exclusive of one another. Because the Ersek sleeve 16 does not have a smooth outer surface, it can not be intraluminally delivered, as that term is understood by persons of skill in the art (Andros Declaration, paragraphs 16 and 21).

The Andros declaration, which Cordis cited to the examiner, stated that the term "smooth," as used to refer to the outer wall surface of a stent of the type disclosed in the '762 patent, "is understood by those skilled in the art to mean that the wall surface is not rough and does not have outwardly projecting edges that would preclude intraluminal delivery and deployment of a low-profile graft from a remote location through a body passageway

to the desired location." Moreover, Cordis called the examiner's attention to this court's decision in *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 450 (Fed.Cir.1986), in which the court held that the term "smooth" should be defined functionally, i.e., "that smooth means smooth enough to serve the inventor's purpose." The clear purpose of the invention in this case, Cordis noted, was "to provide a low-profile, small diameter product that is smooth enough that it can be intraluminally delivered from a remote location to a desired location without the risk of damaging the body passageway." Cordis further explained that, as indicated in the Andros declaration, the term "smooth" means "an absence of roughness that would make it inappropriate to deliver an Ersek-type device by catheterization." Finally, for "further examples of the meaning and common understanding of the term 'smooth surface'" Cordis referred the examiner to an article co-authored by the designer of the NIR stent in a publication entitled *Handbook of Coronary Stents*, which referred to the NIR stent as having a "smooth surface." *See* Kobi Richter, Yaron Almagor, and Martin Leon, *The NIR Stent, Transforming Geometry, in* Patrick W. Serruys & Michael J.B. Kutryk, *Handbook of Coronary Stents* 134 (2d ed. 1998).

That evidence from the prosecution history plainly indicates that the patentee intended for the term "smooth" to be defined functionally, so that a stent would be considered "smooth" if it was smooth enough to be capable of intraluminal delivery. While Cordis also referred to the term "smooth" as meaning not rough,

i.e., not having "bumps, projections, etc.," Cordis made clear at several points in the prosecution history that the concept of roughness, as used in the context of vascular grafts, meant having an outer surface insufficiently smooth to enable intraluminal delivery.

BSC argues that to construe the term "smooth" in this fashion would render the "smooth surface" limitation superfluous, as another limitation of claim 23 requires that the vascular graft have "a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen." In fact, however, a functional definition of smoothness would not render that limitation superfluous, because the "first diameter" limitation relates to the diameter of the graft in its compressed form (i.e., sufficiently small to permit intraluminal delivery), not to its smoothness.

Because there is no dispute that the NIR stent is capable of intraluminal delivery, and in light of the reference in the prosecution history characterizing the NIR stent itself as "smooth," we conclude that under the proper instruction, a reasonable jury would have had to conclude that the NIR stent literally infringed the "smooth surface" limitation. For that reason, we hold that the district court properly denied BSC's motion for JMOL with respect to the "smooth surface" limitation and that BSC was not prejudiced by the district court's finding that Cordis had rebutted the presumption that it had surrendered all equivalents for that limitation.

Although BSC has argued that we should not adopt the broader definition of "smooth surface" urged by Cordis, BSC contends that if we do accept that definition, it would be entitled to a new trial on the issue of obviousness in light of the broader scope of the asserted claim. BSC is correct, of course, that the definition of "smooth surface" that applies to the infringement analysis must also apply to the issue of obviousness. Whether, on the facts of this case, the broader definition requires any further proceeding with respect to the issue of obviousness, however, is not a matter that the parties have addressed in any detail on appeal and is best left for the district court to resolve on remand, particularly in light of the district court's intimate familiarity with the extensive and complex proceedings in this difficult case.

C

BSC next argues that the wall surface of its NIR stent does not exhibit "substantially uniform thickness," and that the district court erred in not granting judgment as a matter of law based on that issue.

The only infringement issue that was in dispute at the 2005 trial was whether the NIR stent literally infringes the "substantially uniform thickness" limitation. BSC and Cordis included statements in a joint pretrial stipulation that made clear the scope of the

dispute that the parties agreed would be at issue in the 2005 trial:

> 8. For the purposes of this trial, it is admitted that the NIR stent as a whole meets the limitations in claim 23 of the '762 patent that require a "tubular member" having a "wall surface," either literally or under the doctrine of equivalents, but it is not admitted that a "C-region" of the NIR stent meets the "tubular member" limitation.
>
> 9. For the purposes of this trial, it is admitted that the NIR stent meets each limitation of claim 23 of the '762 patent, either literally or under the doctrine of equivalents, except for the "substantially uniform thickness" limitation.

The district court issued the following construction of "substantially uniform thickness" to reflect our decision in *Cordis I*: "The wall of a tubular member must be of largely or approximately uniform thickness." BSC did not challenge that claim construction. Applying that construction to the NIR stent, the jury returned a verdict of literal infringement of that limitation.

On appeal, BSC argues that Cordis did not present any evidence that the NIR stent has a uniformly thick wall, and that instead Cordis only presented evidence that the struts of the NIR stent have uniform thickness. In essence, BSC challenges Cordis's approach to

measuring the thickness of the stent wall. It argues that the correct approach to measuring the thickness of the NIR stent's wall requires measuring from each point on the stent's outer surface to a corresponding point on an unvarying cylindrical plane generally defined by the inner boundary of the stent wall. When thickness is measured according to that method, BSC argues, the protruding U-loops and the weld spots produce variations in the thickness of the stent's wall that fall outside the literal scope of the "substantially uniform thickness" limitation.

We reject BSC's argument. The district court's claim construction, to which BSC did not object, did not specify how a person of ordinary skill in the art would determine wall thickness. That was left for the jury to decide as a question of fact, and the jury was entitled to rely on expert testimony that measuring the metal struts provides the correct measurement of wall thickness. Dr. Buller, an interventional cardiologist who testified for Cordis, stated that he understood the stent walls to be the "metal of the stent." Another of Cordis's experts, Dr. Richter, testified that he "would agree that the metal is what defines the wall." Even one of BSC's experts, Dr. Snyder, stated, "As a cardiologist, I would take [the thickness of the wall of a stent] to mean the thickness of the metal from which it was constructed." From that evidence, the jury could reasonably conclude that the thickness of the metal struts was the proper measure of the thickness of the stent wall. That is particularly true in light of the inconsistency in the way the outer and inner portions of the stent wall are treated under

Appendix A

BSC's method of measuring wall thickness. BSC's approach takes account of the U-loops when determining the outer surface, but not when determining the inner surface, which accounts for the asserted variation in the thickness of the stent wall. The figure below shows measurements of wall thickness according to BSC's approach. The outer surfaces of the U-loops are outlined by the dotted line, and the empty space underneath the U-loops is included in BSC's measurement of wall thickness.

Appendix A

BSC argues that during reexamination Cordis disclaimed equating the thickness of the stent wall with the thickness of the metal struts. In addressing the wall thickness limitation, the examiner characterized the fixation sleeve of the Ersek patent as having a uniform wall thickness because the elongate members of the sleeve, "although twisted, have the same thickness as the remainder of the sleeve." The examiner explained that the sleeve was formed from a sheet of metal having uniform thickness "and the twisting of the members . . . does not change their thickness." Cordis responded by arguing that the wall of the Ersek sleeve is of varying thickness "because the strands of the sleeve have twisted out of the plane of the starting material." Noting that the bridges at the junctions of the strands in the Ersek sleeve protrude inwardly and outwardly of the plane of the starting material, Cordis argued that the Ersek sleeve "has a non-uniform wall of varying thickness." As Cordis further explained, the "bridge portions" of the Ersek sleeve "are several times as thick as the strands." Figure 5 of the Ersek patent, shown below, displays the bridge portions (22) having thickness twice as great as the strands in between.

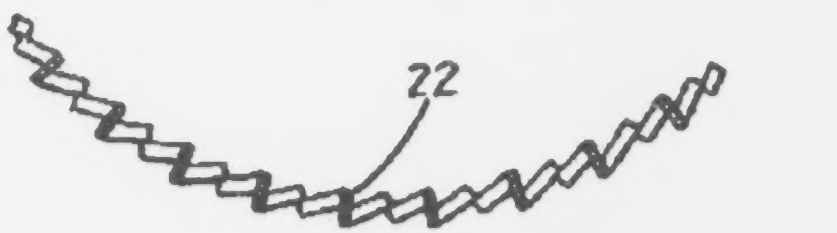


FIG. 5

Appendix A

Cordis's statements during reexamination do not constitute a clear and unequivocal disclaimer of claim scope, as BSC contends. Read in context, those comments are best understood to mean that the intentional deformation of the metal strands in the Ersek sleeve results in certain portions of the wall of the sleeve being much thicker than other portions, as measured from a point along the center line of the sleeve, i.e., the sleeve's longitudinal axis. The comments do not, as BSC argues, require that the measurement of thickness include not only the metal of the U-loops but also the space underneath the U-loops. Instead, they reflect the view that the thickness of the stent wall is a function of the thickness of the metal segments making up the wall. That was the point of the observation that the portions of the Ersek sleeve designated as "bridges" have double thickness when measured from the center line of the stent, even though they are part of the same sheet of metal as the portions designated as "strands." In that respect, the prosecution history does not support BSC's proposed method of measuring wall thickness, which includes counting the space underneath the U-loops as part of the wall. Nor does it support BSC's contention that Cordis clearly and unambiguously disavowed its theory that the thickness of the metal struts should determine the thickness of the stent wall surface.

BSC further contends that it was prejudiced by the district court's answer to a question from the jury regarding the construction of "wall surface" and that it is entitled to a new trial on that ground. During

deliberations, the jury asked the trial judge to "clarify further the words 'disposed' and 'common cylindrical plane' in the definition of wall surface." After a telephonic conference with the parties, the judge gave the jury the following instruction:

> The claim language in the case was previously determined. I cannot define them further.
>
> Let me remind you that the "wall surface" limitation is not in dispute in this case. The only limitation in dispute in this case is the "substantially uniform thickness" limitation.

BSC argues that the court's instruction was prejudicial because it suggested to the jury that the "wall surface" limitation was literally infringed and it implied that the NIR stent's wall surface is disposed in a common cylindrical plane. The instruction, however, said nothing about whether the "wall surface" limitation had been met literally or by equivalents. Moreover, during the telephonic conference, the judge asked BSC's counsel if it was correct to say that the "wall surface" limitation was not in dispute, and BSC's counsel confirmed that it was. That response was consistent with the pretrial stipulation in which Cordis and BSC agreed that for the purposes of the 2005 trial the "wall surface" limitation was to be considered met literally or under the doctrine of equivalents. In light of the limits the parties had agreed to place on the issues presented to the jury for purposes of the infringement inquiry, the court's handling of the jury's question was entirely appropriate.

D

Finally, BSC challenges two of the court's evidentiary rulings that bore on the issue of obviousness. At the 2005 trial, Cordis introduced evidence pertaining to the intraluminal delivery of stents on angioplasty balloons in an effort to distinguish the structure of claim 23 from the structure disclosed in the Ersek patent, which is incapable of intraluminal delivery. Because claim 23 is an apparatus claim rather than a method claim, BSC sought to introduce evidence regarding several of the '762 patent's unasserted method claims that include an intraluminal delivery step and other patent claims involving flexible stents. BSC argues that it needed to introduce that evidence to point out the differences between those other claims and claim 23 of the '762 patent so as to focus the jury on the obviousness of claim 23 and to counter Cordis's evidence as to the general success of the balloon expandable coronary stent. The district court, however, excluded the proffered evidence under Federal Rule of Evidence 403, which authorizes trial courts to exclude evidence when its probative value is substantially outweighed by factors such as delay, the danger of unfair prejudice, or the risk of introducing confusion or misleading the jury. Because the evidence BSC sought to introduce did not focus on claim 23, the only asserted claim in the 2005 trial, it was within the district court's discretion to exclude that evidence out of concern that it would confuse the jury. We are not persuaded that the evidence of other patents and claims was needed in order to give the jury an adequate basis for assessing the question of the obviousness of the invention recited in claim 23.

BSC also sought to introduce evidence about Cordis's interest in acquiring the rights to the NIR stent from BSC. Cordis had introduced evidence of commercial success, and BSC sought to rebut any connection between claim 23 and the commercial success of Cordis's stents by demonstrating that Cordis's commercial success was due mainly to its stent's flexibility, a feature not covered by claim 23. BSC argued that it should have been permitted to introduce evidence of Cordis's plans to purchase the rights to the NIR stent because of the NIR stent's superior flexibility. The district court excluded that evidence under Rule 403 based on the court's conclusion that the commercial success of the NIR stents had limited probative value in determining the obviousness of claim 23. That evidence was relevant in the 2000 trial, because in that trial the doctrine of equivalents was asserted, and the NIR stent's greater flexibility related to BSC's argument against a finding of equivalency. But with respect to the issue of obviousness, the district court properly focused the jury's attention on the prior art and the claimed invention instead of the accused device. It was not an abuse of discretion for the court to exclude the evidence proffered by BSC regarding the properties of the accused device.

IV

In its cross appeal, Cordis challenges the district court's invalidation of claim 44 of the '762 patent under 35 U.S.C. § 305. Section 305 permits the owner of a patent that is in reexamination "to propose any

amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301 of this title, or in response to a decision adverse to the patentability of a claim of a patent." As a limitation on a patent owner's ability to add or amend claims, section 305 provides that "[n]o proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding."

Cordis added claims 44 through 59 to the '762 patent during reexamination in an amendment responding to an office action that was mailed on June 1, 1998. That office action rejected all but two of the claims of the '762 patent as obvious or anticipated in light of various prior art references. In the July 21, 1998, amendment filed in response to that office action, Cordis made a number of changes, including canceling some claims, modifying others, and adding claims 44 through 59. All of those changes were stated to be "[r]esponsive to the Office Action mailed June 1, 1998." Cordis stated in the response that "claims 44-59 are all narrower in scope than the original claims, and provide specific protection for aspects of the disclosed invention which have been incorporated into competitive products and methods."

At trial, the district court submitted the issue of invalidity under section 305 to the jury but reserved decision on whether that issue was ultimately a question for the court. After the jury returned a verdict holding the claims invalid, the district court determined that invalidity under section 305 should be decided by the

court rather than the jury. Using the jury verdict as an "advisory opinion," the court nevertheless found claim 44 invalid because, in its view, claim 44 was not added "(1) to distinguish the invention as claimed from the prior art" or "(2) in response to a decision adverse to the patentability of a claim of a patent" as required by section 305. To the contrary, the court concluded that claim 44 was "added solely to cover competitors' stents, and not for a permissible reason under § 305."

In holding claim 44 invalid, the district court incorrectly interpreted section 305. The portion of section 305 on which the district court relied permits a patentee to add claims (1) that distinguish the invention from the prior art cited under section 301 and (2) that are added in response to an office action adverse to the patentability of a claim. Claims added under either clause must satisfy section 305's substantive limitation, which prevents patent owners from adding new claims that enlarge the scope of the patent's coverage.

Cordis specifically stated that the changes it made in its July 21, 1998, submission to the PTO, including the addition of claims 44 through 59, were "[r]esponsive to" the office action that had rejected all but two of the claims of the '762 patent in light of prior art references. Moreover, Cordis was free to include the new claims even apart from the office action if they were added to distinguish the invention from prior art cited under section 301. Section 305 does not require the patent owner to include an express statement that the new claims distinguish the prior art or remarks indicating

how the new claims distinguish the prior art references. If the claims fail to distinguish the prior art, the claims will be rejected on the appropriate grounds; for that reason, it may frequently be in the patent owner's interest to include such remarks, but they are not necessary to satisfy section 305. For purposes of assessing validity under section 305, the MPEP directs the examiner to determine only whether any added claims impermissibly "enlarge the scope of the original claims." 37 C.F.R. § 1.552(b). Here, the district court acknowledged, and BSC concedes, that claim 44 does not broaden the scope of coverage of the '762 patent.

Because we reverse the judgment with respect to claim 44, we address an issue that BSC raised in a letter submitted on October 1, 2007, after the briefs in this case were filed. In the letter, BSC asked this court to review the judgment of infringement of claim 44 based on the decision of this court in *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed.Cir.2007), which was decided after all the briefs were filed in this case, but before oral argument. BSC's effort to raise a new argument with respect to that issue comes too late. Although BSC challenged the judgment of infringement of claim 44 based on the district court's construction of "slots," which we affirm, BSC did not challenge any findings relating to its connection to or control over the infringing activity. Therefore, BSC has waived review of that issue. *See Engel Indus., Inc. v. Lockformer Co.*, 166 F.3d 1379, 1383 (Fed.Cir.1999).

Appendix A

V

Cordis has asked this court to direct the district court to reinstate the damages verdicts from the 2000 trial. We decline to do so because there may be other issues that need to be addressed before a final judgment can be entered in these cases. For example, we have noted that the district court may have to revisit the issue of obviousness raised by BSC at the 2005 trial in light of the revised claim construction we have adopted for the term "smooth surface." For another, we note that the district court stated at one point that a new trial on damages may be required to determine whether other stents can be considered noninfringing alternatives under the construction of "substantially uniform thickness" from AVE's prior appeal. There may be other matters that we are not aware of that the district court needs to address before it can bring these long-running cases to final judgment. In light of the protracted and complex proceedings in the district court, the district judge is in a far better position than we are to determine what remains to be done to bring these matters to a close.

AFFIRMED IN PART, REVERSED IN PART, and REMANDED.

APPENDIX B — MEMORANDUM OPINION OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE DATED SEPTEMBER 21, 2004

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Civil Action No. 97-550-SLR
(consolidated)

CORDIS CORPORATION,

Plaintiff,

v.

MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,

Defendants.

Civil Action No. 97-700-SLR

MEDTRONIC AVE, INC.,

Plaintiff,

v.

CORDIS CORPORATION, JOHNSON & JOHNSON and EXPANDABLE GRAFTS PARTNERSHIP,

Defendants.

Appendix B

Civil Action No. 98-19-SLR

BOSTON SCIENTIFIC CORPORATION,

Plaintiff,

v.

ETHICON, INC., CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants.

Civil Action No. 98-197-SLR

CORDIS CORPORATION,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,

Defendants.

MEMORANDUM OPINION

ROBINSON, Chief Judge.

I. INTRODUCTION

The above captioned litigation has a long and convoluted history, which will not be repeated at any length

in this opinion. Upon remand from the Federal Circuit, *see Cordis Corp. v. Medtronic Ave, Inc.*, 339 F.3d 1352 (Fed.Cir.2003), I was directed, *inter alia*, to amend my claim construction of the "substantially uniform thickness" limitation consistent with the guidance given by the appellate court. I did so by order dated February 17, 2004.[1]

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1. In my February 17, 2004 order, I construed the "substantially uniform thickness" limitation as meaning that "the thickness of the wall of the stent be largely or approximately uniform along its length and between members to allow uniform expansion of the stent." (D.I. 1201 at 6) Plaintiff has filed a motion for reconsideration based, *inter alia*, on the Federal Circuit's discussion of the "substantially uniform thickness" limitation in subsequent litigation involving some of the same parties and some of the same technology, *Cordis Corp. v. Boston Scientific Corp.*, 99 Fed.Appx. 928 (Fed.Cir.2004). (D.I.1231, ex. A) More specifically, the panel in the above cited case characterized its revised claim construction in this case as follows: "[T]his court revised the construction of 'substantially uniform thickness' to mean that 'the walls must be of largely or approximately uniform thickness' and that 'a wall that varies in thickness by as much as 100 percent cannot be said to be of 'substantially uniform thickness' either literally or by equivalents.' " *Id.* at 933 (citing *Cordis Corp. v. Medtronic Ave, Inc.*, 339 F.3d at 1360, 1362). The panel did not refer in its discussion to the added requirement that "the thickness of the wall surface be sufficiently uniform along its length and between members to allow uniform expansion of the stent," as had the court in this case. *Cordis Corp. v. Medtronic Ave, Inc.*, 339 F.3d at 1360.

Having reflected further on this matter, in light of the Federal Circuit's discussion (not binding, of course) and in light of the other limitations which have not been construed to add a

(Cont'd)

(D.I.1201)[2] Before me presently are the motions for partial summary judgment on amendment-based prosecution history estoppel filed by Medtronic AVE, Inc., Boston Scientific Corporation and Scimed Life Systems, Inc. ("defendants"). For the reasons that follow, I conclude that plaintiff Cordis Corporation is not estopped from seeking infringement by equivalents. Therefore, defendants' motions shall be denied.

II. LEGAL STANDARD

The United States Supreme Court, in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002), reaffirmed the vitality of the doctrine of equivalents: "The scope of a patent is not limited to its literal terms

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(Cont'd)
functional element, the motion for reconsideration is granted. The "substantially uniform thickness" limitation shall be construed to mean that the walls "must be of largely or approximately uniform thickness."

The other limitation at issue is the "smooth surface" limitation, construed as meaning that the "outside of the wall surface of the unexpanded tubular member has a continuously even surface, without roughness, points, bumps or ridges, especially to the touch." (D.I. 1127 at 9) As noted above, there is no functional limitation in the construction, e.g., the wall surface must be smooth enough to accommodate intraluminal delivery.

2. All docket item numbers in this opinion refer to the docket in the lead case, *Cordis Corp. v. Medtronic AVE, Inc., et al.*, Civ. No. 97-550-SLR (consolidated).

but instead embraces all equivalents to the claims described." *Id.* at 732, 122 S.Ct. 1831. As explained by the Court,

> [i]t is true that the doctrine of equivalents renders the scope of patents less certain. It may be difficult to determine what is, or is not, an equivalent to a particular element of an invention. If competitors cannot be certain about a patent's extent, they may be deterred from engaging in legitimate manufactures outside its limits, or they may invest by mistake in competing products that the patent secures. In addition the uncertainty may lead to wasteful litigation between competitors, suits that a rule of literalism might avoid. These concerns with the doctrine of equivalents, however, are not new. Each time the Court has considered the doctrine, it has acknowledged this uncertainty as the price of ensuring the appropriate incentives for innovation, and it has affirmed the doctrine over dissents that urged a more certain rule.

Id.

Having declared "that equivalents remain a firmly entrenched part of the settled rights protected by the patent," *id.* at 733, 122 S.Ct. 1831, the Supreme Court went on to discuss the limits placed on the doctrine of equivalents by prosecution history estoppel.

Appendix B

> Prosecution history estoppel ensures that the doctrine of equivalents remains tied to its underlying purpose. Where the original application once embraced the purported equivalent but the patentee narrowed his claims to obtain the patent or to protect its validity, the patentee cannot assert that he lacked the words to describe the subject matter in question. The doctrine of equivalents is premised on language's inability to capture the essence of innovation, but a prior application describing the precise element at issue undercuts that premise. In that instance the prosecution history has established that the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter.

Id. at 734-735, 122 S.Ct. 1831. In other words, the prosecution history of a patent, as the public record of the patent proceedings, serves the important function of identifying the boundaries of the patentee's property rights. Once a patentee has narrowed the scope of a patent claim as a condition of receiving a patent, the patentee may not recapture the subject matter surrendered.

Appendix B

In order to determine what equivalents are included within the scope of the subject matter surrendered by a narrowing amendment, the Supreme Court has been mindful of

> the purpose of applying the estoppel in the first place—to hold the inventor to the representations made during the application process and to the inferences that may reasonably be drawn from the amendment. By amending the application, the inventor is deemed to concede that the patent does not extend as far as the original claim. It does not follow, however, that the amended claim becomes so perfect in its description that no one could devise an equivalent. After amendment, as before, language remains an imperfect fit for invention. The narrowing amendment may demonstrate what the claim is not; but it may still fail to capture precisely what the claim is. There is no reason why a narrowing amendment should be deemed to relinquish equivalents unforeseeable at the time of amendment and beyond a fair interpretation of what was surrendered. Nor is there any call to foreclose claims of equivalence for aspects of the invention that have only a peripheral relation to the reason the amendment was submitted. . . .

Id. at 737-738, 122 S.Ct. 1831. The Court concluded that "the patentee should bear the burden of showing that

the amendment does not surrender the particular equivalent in question." *Id.* at 740, 122 S.Ct. 1831. Although "[a] patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim," a patentee may overcome the presumption that prosecution history estoppel bars a finding of equivalence by demonstrating, *inter alia*, that "the rationale underlying the amendment [bears] no more than a tangential relation to the equivalent in question." *Id.*

The reason for applying the principles of prosecution history estoppel to claims that have been narrowed by amendment has been expanded to include all of the patent claims containing the narrowing limitation, regardless of whether they themselves were ever amended. This theory of "infectious estoppel" generally is credited to the analysis of the Federal Circuit in *Builders Concrete, Inc. v. Bremerton Concrete Products Co.*, 757 F.2d 255 (Fed.Cir.1985). In that case, claim 1 of the patentee's application was amended to include certain "passage limitations" originally included in application claims 2 and 11. The amendment was made in view of the prior art. Although application claim 11 was the only claim at issue and had always included the "passage limitations," the Federal Circuit concluded that the patentee was estopped

> from interpreting application claim 11 (patent claim 10) to encompass that which was relinquished in the successful argument for

> patentability of amended claim 1. Although claim 10 is the only claim in suit, the prosecution history of all claims is not insulated from review in connection with determining the fair scope of claim 10. To hold otherwise would be to exalt form over substance and distort the logic of this jurisprudence, which serves as an effective and useful guide to the understanding of patent claims. The fact that the "passage" clause of patent claim 10 was not itself amended during prosecution does not mean that it can be extended by the doctrine of equivalents to cover the precise subject matter that was relinquished in order to obtain allowance of claim 1. It is clear from the prosecution history that the allowance of claim 1, the broadest claim with respect to the other elements of the float, depended on the amendment narrowing its "passage" definition to that of claim 10.

Id. at 260.

III. DISCUSSION

In accordance with the above standards, it is plaintiff's burden to demonstrate, by a preponderance of the evidence, that the rationale underlying the amendments bears no more than a tangential relation to the equivalents in question.

Appendix B

A. Prosecution History

All the asserted claims of the '762 patent—claims 23, 51 and 54—contain or incorporate limitations requiring that the wall surface have a "substantially uniform thickness" and be "smooth." Claim 23 included these limitations from the outset;[3] other claims (e.g., independent claims 35 and 37) omitted those limitations.

In October 1997, plaintiff filed a reexamination request for the '762 patent in which it identified several patents that had not been of record in the original prosecution, including the Ersek '744 patent. In its request for reexamination, plaintiff distinguished independent claim 13 from the Ersek fixation sleeve by describing the latter device as being "neither designed nor intended to be delivered intraluminally into a body passageway because of its having sharp projecting edges in its first diameter prior to its expansion." (DX 2074 at PWRAP 1434) With respect to dependent claim 23, plaintiff described "the outside surface of the Ersek fixation sleeve [as having] narrow, outwardly projecting

---

3. Claim 23 originally depended from claim 13. Claim 13 included the "substantially uniform thickness" limitation; dependent claim 23 added the "smooth surface" limitation. During the reexamination process, claim 13 was amended to include the "smooth surface" limitation and claim 23 was cancelled. Ultimately, claim 13 was cancelled, the cancellation of claim 23 was cancelled, and claim 23 became an independent claim with all the limitations of cancelled independent claim 13. (AVE trial exhibit 2074, "DX 2074", at PWRAP 1458-1459, PWRAP 3039, PWRAP 3243)

edges when in its first diameter and does not have a smooth outside wall surface." (*Id.* at PWRAP 1436)

On June 1, 1998, the examiner issued an office action in which he rejected several claims over the prior art that included Ersek. As to claim 13, the examiner opined that the Ersek fixation sleeve could be considered an "intraluminal" member because it was implanted within a blood vessel or, alternatively, was capable of being so delivered "by percutaneous insertion into the artery by appropriate instrumentation." (*Id.* at PWRAP 3015-3016) With respect to claim 23, the examiner opined that "the outside of the wall surface of the Ersek tubular member 16 is 'smooth,' " even while acknowledging that "the Ersek members 22 which form the wall are twisted . . . such that the outside of the wall surface is, for the most part, narrow edges rather than the wider surfaces of the ribbon-like members 22." (*Id.* at PWRAP 3016)[4]

---

4. The examiner discussed the "uniform thickness" limitation in connection with dependent claim 6:

> As to claim 6, the thin walled tubular member (the Ersek fixation sleeve) and the elongate members (members 22 in the fixation sleeve) have a uniform wall thickness since the members 22, although twisted, have the same thickness as the remainder of the sleeve. In other words, the sleeve is formed from a sheet of material having uniform thickness and the twisting of the members 22 does not change their thickness.

(*Id.* at PWRAP 3009)

Appendix B

On July 21, 1998, plaintiff filed an amendment in response to the office action in which it added the "smooth surface" limitation to claim 13 and added both the "substantially uniform thickness" and "smooth surface" limitations to claims 35 and 37. It also added, *inter alia*, new claims 51 and 54, which included both limitations. (*Id.* at PWRAP 3039-3044) In its accompanying remarks, plaintiff distinguished the Ersek invention in various ways. First, plaintiff distinguished the Ersek by function: "There is no teaching within the Ersek patent that the sleeve 16 may be utilized to **treat** an obstructed body passageway. The sole and only teaching within the Ersek patent regarding utilization of sleeve 16 is as a **fixation device** in substitution for sutures." (*Id.* at PWRAP 3048) Plaintiff then distinguished Ersek by structure: "To aid in fixation and to resist forces tending to pull out the implanted prosthetic device, the Ersek sleeve has outwardly projecting sharp metal edges." (*Id.*) Plaintiff further described the Ersek sleeve, *inter alia*, as having a "non-uniform wall of varying thickness" and "inner and outer surfaces ... [that] are not smooth." (*Id.* at PWRAP 3049; see also PWRAP 3054-3055, 3057) Finally, plaintiff distinguished Ersek by result: "In contrast to the minimally invasive procedure of Dr. Palmaz, the Ersek patent teaches a method of implanting a prosthesis in a living body during an open surgical procedure" as a substitute for sutures. (*Id.* at PWRAP 3048)

A Notice of Intent to Issue Reexamination Certificate was executed on August 25, 1998. (*Id.* at PWRAP 3252) In explaining his reasons for allowing

claim 23 over Ersek, the examiner stated that, upon reconsideration,

> the outside of the wall surface of the Ersek (3,657,744) fixation sleeve is not considered to be smooth. The Ersek fixation sleeve is formed of expanded metal. A sample of conventional expanded metal was shown to the examiner during the July 8, 1998 interview. The sample is depicted in Exhibit 1 of the July 22, 1998 amendment. The sample has the same basic shape as that shown in figure 5 of Ersek. As one follows the outside surface of one of the strands of the sample, one meets an abrupt obstacle at the bridge (at the junction of the strands) since the ridge has a thickness which is twice as great as the strand. The outside of the wall surface of the Ersek fixation sleeve includes a multitude of these obstacles (one at each bridge), making it rough rather than smooth. Therefore, the Ersek reference fails to meet the smooth surface limitation quoted above. Further, making the outside of the Ersek fixation sleeve smooth rather than rough would be contrary to the teachings of Ersek since the rough surface formed by narrow outwardly projecting edges is intended to embed itself into the tissue wall upon expansion of the sleeve.

(*Id.* at PWRAP 3257-3258)

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B. Analysis

In applying the "tangential relation" criterion, courts are directed by *Festo* and its progeny to focus "on the patentee's objectively apparent reason for the narrowing amendment," as well as "the context in which the amendment was made." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369-1370 (Fed.Cir.2003)(en banc) ("*Festo III* "). If the "reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent," then the "tangential relation" criterion has been satisfied. *Id.* at 1369. Clearly, "an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim." *Id.*

Having reviewed the prosecution history and the papers submitted by the parties, I conclude at the outset that the Ersek prior art does not contain the equivalents at issue. In this regard, I find that the accused devices (stents delivered intraluminally for the treatment of obstructed body passageways) and the Ersek fixation sleeve (a prosthesis implanted during an open surgical procedure as a substitution for sutures) are "disparate devices with no logical connection to one another." (*Id.* at PWRAP 3061-3062) Having found that the prior art device bears no more than a tangential relation to the equivalents at issue, the question remains as to whether the amendments made to distinguish the prior art device should be found to bear more than a tangential relation to those same equivalents.

Appendix B

Defendants argue that "a narrowing amendment will not be considered to be tangentially related if the disputed limitation was 'directly at issue' during prosecution." (D.I. 1234 at 20) If this were the proper standard, then defendants should prevail. Certainly the "substantially uniform thickness" and "smooth surface" limitations were "at issue" during the reexamination proceedings, in that they were added to various claims in order to distinguish Ersek and were discussed in that context. Further, these same limitations are "at issue" in this litigation, as defendants contend that their accused products may be distinguished from the inventive device as not having wall surfaces that are "smooth" or of a "substantially uniform thickness."

Plaintiff argues in response that defendants are not employing the correct inquiry. By focusing on "whether the amendment itself narrows the scope of the claim in a way that affects the equivalent[s] in question," defendants are making superfluous the tangential relation exception to the presumptive bar imposed under *Festo.* As the court observed in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 287 F.Supp.2d 126 (D.Mass.2003): "If this were the test, it would be an impossible one—the only reason why the dispute arises is **because** the equivalent is related to the amendment and thereby affected." *Id.* at 150. According to plaintiff, "[t]he correct inquiry is whether the **rationale** underlying the amendment, the 'reason the amendment was submitted'—not the amendment itself—is more than peripherally related to the equivalent in question." (D.I. 1241 at 29, citing *Amgen,* 287 F.Supp.2d at 150)

In this case, the reason the amendments were submitted was to distinguish a prior art device that is only tangentially related to either the inventive or the accused devices. More specifically, with respect to the "substantially uniform thickness" limitation, the Federal Circuit in this case found that, "[i]n addressing Ersek, Cordis focused on the double thickness of the bridge portions of Ersek's walls;" "Cordis's basis for distinguishing Ersek appears to have been that Ersek's walls were at least twice as thick at the intersections of strands as along the strands themselves." *Cordis,* 339 F.3d at 1361. As concluded by the Federal Circuit, "a wall that varies in thickness by as much as 100 percent cannot be said to be of 'substantially uniform thickness' either literally or by equivalents." *Id.* at 1362. Similarly, in distinguishing the Ersek device as lacking a "smooth surface," plaintiff focused on the "outwardly projecting edges" of the Ersek device which were intended to "embed themselves into the vessel wall to hold the sleeve 16 and its associated graft in place," not for the intraluminal delivery of the sleeve 16 through the vascular system. (DX 2074 at PWRAP 3049, 3055)[5]

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5. The facts of record are very different from those reviewed in *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 347 F.3d 1355 (Fed.Cir.2003). In that case, the patentee added a temperature range in order to distinguish prior art references with higher temperature ranges. The accused product had a temperature range between that claimed and that of the prior art references. The Federal Circuit held that the patentee could not assert the doctrine of equivalents because of amendment based prosecution history estoppel: "[T]he reason for Talbert's

(Cont'd)

Clearly the structure of the Ersek device is the antithesis of the equivalent structures at issue.

IV. CONCLUSION

The doctrine of equivalents remains fertile ground for litigation, as it is often difficult to harmonize this jurisprudence with the particular facts presented. In this case, consistent with the compelling facts of record and the equitable principles discussed above, I conclude that plaintiff is not estopped from seeking infringement by equivalents. Therefore, defendants' motions for partial summary judgment on amendment-based estoppel are denied. An appropriate order shall issue.

(Cont'd)

amendment cannot be deemed 'tangential' to the Unocal alleged equivalent. The boiling range and carbon content were at issue during prosecution, and were the direct, not tangential, reason for the narrowing amendments to these claim limitations." *Id.* at 1360. In other words, in *Talbert,* the narrowing amendment was made to avoid prior art that "embrace[d] the alleged equivalent." *Id.* at 1359. In contrast, the amendment at bar was made to distinguish a reference (Ersek) that does not contain the structure of the equivalents in dispute.

APPENDIX C — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE DATED MARCH 28, 2002

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Civil Action No. 97-550-SLR
(consolidated)

CORDIS CORPORATION,

Plaintiff,

v.

MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,

Defendants.

Civil Action No. 97-700-SLR

MEDTRONIC AVE, INC.,

Plaintiff,

v.

CORDIS CORPORATION, JOHNSON & JOHNSON and EXPANDABLE GRAFTS PARTNERSHIP,

Defendants.

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Civil Action No. 98-19-SLR

BOSTON SCIENTIFIC CORPORATION,

Plaintiff,

v.

ETHICON, INC., CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants.

Civil Action No. 98-197-SLR

CORDIS CORPORATION,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,

Defendants.

OPINION

Dated: March 28, 2002
Wilmington, Delaware

s/ Sue L. Robinson
ROBINSON, Chief Judge

Appendix C

I. INTRODUCTION

Plaintiffs Expandable Grafts Partnership and Cordis Corporation, a division of Johnson & Johnson (collectively, "Cordis"), originally filed this patent infringement action on October 3, 1997 against defendants Medtronic AVE, Inc., Boston Scientific Corporation and Scimed Life Systems, Inc.[1] Cordis alleges that AVE infringed certain claims of United States Patent Nos. 4,739,762 (the " '762 patent") and 5,195,984 (the " '984 patent"). Cordis accuses BSC of infringing certain claims of the '762 patent and United States Patent Nos. 5,902,332 (the " '332 patent"), 5,643,312 (the " '312 patent"), and 5,879,370 (the " '370 patent"). The court held a seven-week bifurcated jury trial on the issues of infringement and invalidity, and a four-day bench trial on the issue of unenforceability. Currently before the court are the parties' motions for judgment as a matter of law and a new trial, and proposed findings of fact and conclusions of law regarding inequitable conduct.

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1. Defendant Medtronic AVE, Inc. will be referred to as "AVE." Defendants Boston Scientific Corporation and Scimed Life Systems, Inc. will be referred to collectively as "BSC." Advanced Cardiovascular Systems, Inc. ("ACS") was originally a defendant, but entered into a stipulated order of dismissal with Cordis prior to trial. (D.I. 705)

Appendix C

II. BACKGROUND

A. The Technology

The dispute relates to balloon expandable stents. Balloon expandable stents and other types of stents are used to treat diseased blood vessels in the heart ("coronary arteries") and in other areas of the body ("peripheral arteries"). Coronary artery disease is caused by the buildup of fatty deposits on the inner lining of the coronary arteries. Known as atherosclerosis, this buildup narrows coronary arteries and may eventually block the flow of blood to the heart. Untreated coronary disease can have serious consequences, including angina, heart attack or even death. Similar narrowing in arteries away from the heart causes problems for people with peripheral artery disease.

Until about twenty-five years ago, the primary treatment for coronary lesions was medication or coronary artery bypass graft surgery. In approximately 1975, physicians began to use a non-surgical treatment called percutaneous transluminal coronary angioplasty, commonly known as "balloon angioplasty." During this procedure, a balloon attached to a wire catheter is snaked through a diseased artery until it reaches the site of blockage. A physician inflates the balloon, which compresses the fatty deposits against the vessel wall to open the artery and restore blood flow. The balloon and catheter are then removed from the body. Although balloon angioplasty represented a major advancement in combating artery disease, blood vessels often closed

again within several months of the procedure. This recurrence of blockage is called "restenosis."

A stent improves the success of balloon angioplasty by minimizing the occurrence of restenosis. A stent is a small device that holds open an artery just like scaffolding inside a tunnel keeps the tunnel from collapsing. At issue in this case are balloon expandable stents which are used in conjunction with angioplasty balloons. The stent is placed on a balloon and inserted into an artery via a catheter. Once the balloon is at the area of blockage, it is inflated, which causes the stent to expand and press against the vessel wall, thereby opening the artery. The balloon is then deflated and removed, leaving the expanded stent in the artery to keep the vessel open and allow blood to flow.

B. The Patents in Suit

1. The '762 Patent

The '762 patent, entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft," is a continuation-in-part of patent application serial no. 796,009 (the " '009 application"), which issued as United States Patent No. 4,733,665 (the " '665 patent"). Dr. Julio C. Palmaz is the named inventor of the '762 patent, and plaintiff Expandable Grafts Partnership ("EGP") is the listed assignee. Dr. Palmaz filed the '009 application on November 7, 1985, and the '762 patent issued on April 26, 1988. A reexamination certificate (the " '762

reexamination certificate") issued on October 27, 1998 with amended and additional claims.

The '762 patent includes both apparatus and method claims. The apparatus claims are directed to an expandable tubular member that serves as vascular scaffolding. Figures 1A and 1B shown below depict the preferred embodiment of the '762 patent in its unexpanded state ("first diameter") and expanded state ("second diameter"), respectively.

Fig. 1A

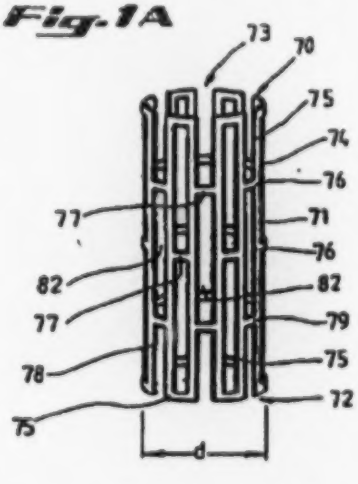
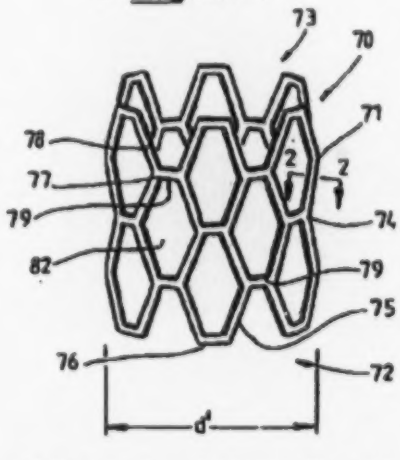


Fig. 1B



The method claims of the '762 patent describe the process of implanting the stent into a diseased vessel. As depicted in Figures 3 and 4 below, a stent is mounted upon a catheter and delivered in its first diameter to the diseased vessel. Next, the stent is expanded and deformed radially into contact with the vessel. Finally, the balloon is deflated and removed along with the catheter, leaving the stent in the artery to support the vessel wall.

Appendix C

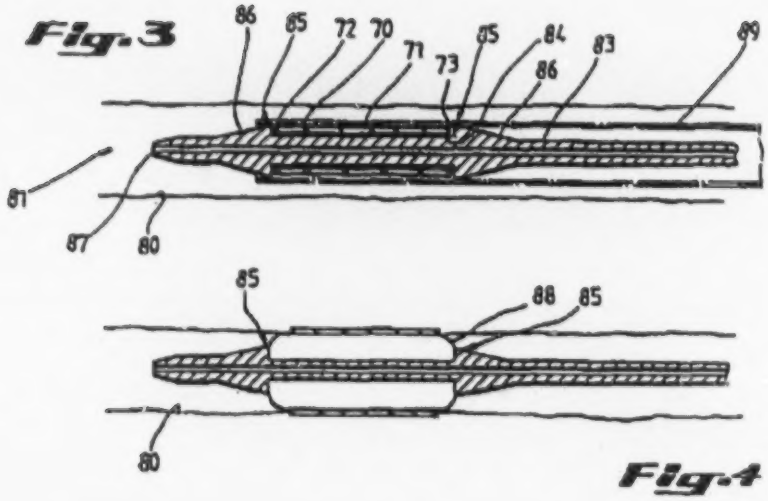


Fig. 4

Claim 23 of the '762 patent is an apparatus claim which is dependent upon claim 13.[2] The claims read:

> 13. An expandable intraluminal vascular graft, comprising:
>
> a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

---

2. Claim 13 was cancelled during reexamination of the '762 patent. ('762 reexamination certificate, col. 1, ln. 34)

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

23. The expandable intraluminal vascular graft of claim 13, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

('762 patent, col. 11, ln. 63 - col. 12, ln. 14; col. 12, lns. 56-59)

Claim 44, a method claim added during reexamination, reads:

44. A method for implanting a balloon expandable stent prosthesis within a passageway of a coronary artery having an area of stenosis, comprising the steps of:

utilizing a thin-walled, tubular member as the stent prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

disposing the stent prosthesis and catheter having an inflatable balloon portion;

inserting the stent prosthesis and catheter within the passageway by percutaneous catheterization;

delivering the catheter and stent prosthesis to the area of stenosis without surgically exposing the area of the passageway; and

expanding and deforming the stent prosthesis at the area of stenosis within the coronary artery passageway by expanding the inflatable balloon portion of the catheter associated with the stent prosthesis to force the stent prosthesis radially outwardly into contact with the area of stenosis in the passageway, the stent prosthesis being controllably deformed beyond its elastic limit.

('762 reexamination certificate, col. 3, lns. 22-44)

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Claims 51 and 54, also added during reexamination, read:

> 51. In combination, a balloon expandable stent prosthesis for implementation in the passageway of a coronary artery having an area of stenosis and a catheter comprising:
>
> an expandable stent prosthesis being a thin-walled tubular member having first and second ends and a wall having an outer wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;
>
> a catheter having an expandable, inflatable balloon portion;
>
> the tubular member having a first diameter which permits intraluminal delivery of the tubular member and the catheter into a lumen of a coronary artery having an area of stenosis and wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter; and
>
> the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular

member of a radially, outwardly extending force, which second diameter is variable and controlled by the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the coronary artery in the area of stenosis.

54. The combination of claim 51, wherein said tubular member includes at least one ring portion defined by circumferentially adjacent slots so as to define a plurality of peak portions and valley portions.

('762 reexamination certificate, col. 4, lns. 4-33, 41-44)

Prior to trial, the court construed disputed terms of the '762 patent as follows:

(1) **"Graft"** and **"Prosthesis."** A graft and prosthesis must be functional, that is, once it is expanded and deformed it must be capable of serving to prevent a body passageway from collapsing.

(2) **"Tubular member."** A discrete structure that has the form of a tube, that is, a hollow, elongated, usually cylindrical structure with two ends. "Elongate" is defined in the dictionary as "stretched out, lengthened; especially: having a form notably long in comparison to its width."

(3) **"Thin-walled."** The wall of the tubular member must have little extent from one surface to its opposite at both its first and second diameters.

(4) **"Wall surface."** The outer surface of the tubular member must be disposed in a common cylindrical plane.

(5) **"Substantially uniform thickness."** The thickness at all points along the wall surface of the tubular member, both at its first and second diameters, must be substantially the same. Variances as little as .001 inches fall outside the scope of "substantially uniform."

(6) **"Plurality of slots."** More than one slot. A "slot" is a long and narrow opening or groove, an opening whose length is substantially greater than its width. The claim requires slots in the tubular members that run substantially parallel to the longitudinal axis.

(7) **"Slots formed therein."** Slots must be formed in the wall surface of a tubular member, as by the removal of material.

(8) **"Smooth surface."** The outside of the wall surface of the unexpanded tubular member has a continuously even surface, without roughness, points, bumps or ridges, especially to the touch.

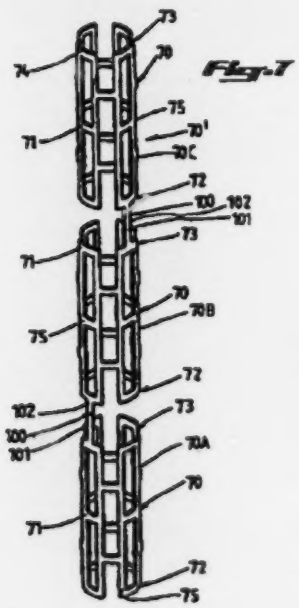
(D.I. 790, 1115, 1116)

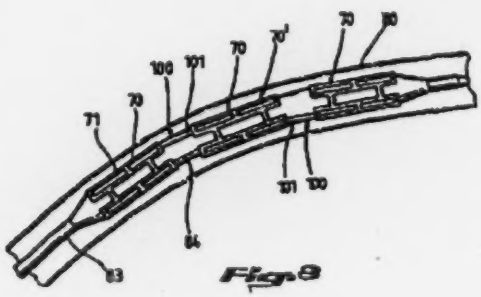
Appendix C

2. The '984 Patent

The '984 patent, entitled "Expandable Intraluminal Graft," was filed on February 19, 1991 as a continuation of abandoned patent application serial number 253,115, filed on October 4, 1988. Dr. Richard A. Schatz is the named inventor, and EGP is the listed assignee. The '984 patent is directed to an improvement upon prior art stents, namely, connecting tubular members to "permit[ ] tissue of an elongated section of a body passageway to be supported by an elongated graft; and provide[ ] the necessary flexibility to negotiate the bends and curves in tortuous body passageways, such as the vascular system." ('984 patent, col. 4, lns. 20-25)

Figures 7 and 8 depict the angularly offset connector members of the '984 patent and the resulting added flexibility in a body passageway.





Appendix C

Claims 1 and 3 of the '984 patent read:

1. An expandable intraluminal vascular graft, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

only one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members, the connector member being disposed in a substantially parallel relationship with respect to the longitudinal axis of the tubular members and coplanar with each tubular member;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the

> tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.
>
> 3. The expandable intraluminal graft of claim 1, wherein a first connector member is disposed between the second end of a first tubular member and the first end of a second tubular member; a second connector member is disposed between the second end of the second tubular member and the first end of a third tubular member, the first and second connector members being angularly offset from one another and with respect to the longitudinal axes of the tubular members they interconnect.

('984 patent, col. 11, ln. 44 - col. 12, ln. 8; col. 12, lns. 13-22)

The court construed disputed terms of the '984 patent as follows:[3]

> (1) **"Only one."** A single unit and no more.
>
> (2) **"Connector member."** A discrete structure disposed or particularly arranged between adjacent tubular members in order to join them together.

---

3. Terms appearing in both the '762 and '984 patents are construed consistently.

(3) **"To flexibly connect adjacent tubular members."** To connect in such a way as to allow turning, bowing or twisting without breaking. The connector member must provide flexibility, whether or not the adjacent tubular members themselves are flexible.

(4) **"Substantially parallel."** The connector member must run in substantially the same direction as the longitudinal axis of the adjacent tubular members. This means that the slots and the connectors run in the same direction and are substantially aligned with one another.

(5) **"Coplanar."** The connector member must lie within the planes formed by the inner and outer wall surfaces of the adjacent tubular members.

(D.I. 790, 1115)

3. The '332 Patent

The '332 patent, entitled "Expandable Intraluminal Graft," was filed on November 24, 1992 as a continuation of patent application no. 07/657,296, which issued as the '984 patent. The specification of the '332 patent, therefore, is virtually identical to that of the '984 patent.

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Claim 22 of the '332 patent reads:

22. A balloon expandable coronary stent for delivery to a coronary artery through an access artery, the stent comprising:

at least two segments, each segment having a generally tubular shape and a first end and a second end;

each segment having a plurality of openings that are disposed substantially parallel to the longitudinal axis of the segment, the openings forming a series of alternating open and closed portions in each of the first and second ends of the segment;

the segments being arranged so that at least one closed portion of the second end of a first segment is in longitudinal alignment with a closed portion of the first end of a second segment;

a connector extending between and connecting the aligned closed portion of the second end of the first segment to the aligned closed portion of the first end of the second segment, the connector being an elongate flexible member that extends between and is integrally formed with the aligned closed portions;

whereby each of the segments may be displaced at an angle with respect to the longitudinal axis of an adjacent segment when the stent is delivered through a curved portion of the access or coronary arteries; and

the stent having a first diameter which permits intraluminal delivery of the stent through the access artery by percutaneous catheterization and a second, expanded and deformed diameter, the second diameter being attained upon the application from the interior of the stent of a radially, outwardly directed force by inflating a balloon, which second diameter is variable and dependent upon the amount of force applied to the stent, whereby the stent may be expanded and deformed beyond its elastic limit to expand the lumen of the coronary artery.

('332 patent, col. 13, ln. 13 - col. 14, ln. 13)

The court construed disputed terms of the '332 patent as follows:

(1) **"Segment."** A piece or separate fragment of something; one of the constituent parts into which a body is or may be divided.

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(2) **"Generally tubular shape."** The phrase "segment having a generally tubular shape" is broader in scope than the phrase "tubular member" and may encompass segments that are not perfectly hollow, elongated or cylindrical in shape.

(3) **"Plurality of openings."** More than one opening, that is, more than one breach or aperture.

(4) **"Openings forming a series of alternating open and closed portions."** All openings have "open" and "closed" portions, the closed portions comprising the material that gives form to or encloses the openings and serves to block or shut off entry or passage in some fashion. The claim requires that the openings in the segment alternate around the circumference so that each end of the segment consists of alternating open and closed portions. The court construes the phrase at issue to mean a combination of openings, some of which are "open," that is, without enclosing material at the end of the segment, thus permitting ingress and egress, and some of which are "closed," that is, having enclosing material at the end of the segment thus blocking or shutting off entry or passage.

(5) **"Connector."** A discrete structure disposed or particularly arranged between

adjacent tubular members in order to join them together. The language of the claim ("comprising . . . a connector") does not require that the claim be limited to a single connector.

(6) **"Whereby each of the segments may be displaced at an angle with respect to the longitudinal axis of an adjacent segment when the stent is delivered through a curved portion of the access or coronary arteries."** "Displaced" means to remove from the usual or proper place, to put out of place. An "angle" is a figure formed by two lines diverging from the same point or by two surfaces diverging from the same line. "Axis" is defined as a straight line with respect to which a body or figure, or system of points is either radially or bilaterally symmetrical. The phrase modifies the word "segment;" the phrase as written indicates that the entire segment (not a portion thereof) must be capable of angular displacement with respect to the longitudinal axis of the adjacent segment (not a portion thereof). In light of the specification, which speaks only in terms of a connector being disposed to flexibly connect rather than in terms of flexible segments, the court concludes that the limitation requires relatively rigid segments and relatively flexible connectors.

(D.I. 790, 1116)

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4. The '312 and '370 Patents

The '312 patent, entitled "Stent Having a Multiplicity of Closed Circular Structures," was filed on February 25, 1994 by inventors Robert E. Fischell, David R. Fischell and Tim A. Fischell. The '370 patent, entitled "Stent Having a Multiplicity of Undulating Longitudinals," was filed on May 28, 1997 as a continuation of patent application serial no. 08/202,128, which issued as the '312 patent. Thus, the '312 and '370 patents have virtually identical specifications. The patents are directed to stents containing generally circular "rings" for radial strength upon expansion and "undulating longitudinals" for added flexibility. (312 and '370 patents, col. 1, lns. 40-55)

Claim 21 of the '312 patent reads:

> 21. A predeployment stent structure adapted for placement in curved vessels of the coronary arteries, the stent structure being in the form of a thin-walled metal cylinder having a longitudinal axis, the stent including at least two undulating longitudinal structures each longitudinal structure having a multiplicity of straight sections and undulating sections with each straight section being joined continuously to at least one undulating section, the straight sections of all of the longitudinal structures being generally parallel to the longitudinal axis of the stent,

> the undulating sections of each longitudinal structure being of a generally curved shape so as to allow each undulating longitudinal structure to readily expand and contract in length when the stent is bent while passing through a curved coronary artery.

(312 patent, col. 7, lns. 4-17)

Claim 25 of the '370 patent is dependent upon claim 22. The claims read:

> 22. A pre-deployment balloon expandable stent structure adapted for percutaneous delivery to the curved coronary arteries, the stent structure being generally in the form of a thin-walled metal tube having a longitudinal axis, the stent structure having a multiplicity of closed perimeter cells, each cell having one or more undulating sections, each undulating section having a generally curved shape and having a first end point and a second end point wherein a line drawn from the first end point to the second end point is generally parallel to the stent's longitudinal axis.
>
> 25. The stent of claim 22 wherein the undulating section of each closed perimeter cell comprises a "U" shaped curve.

('370 patent, col. 6, lns. 17-26, 35-36)

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Claim 26 of the '370 patent reads:

26. A balloon expandable coronary stent comprising:

(a) a stent in the form of a thin-walled metal tube capable of being mounted on an expandable balloon for percutaneous delivery of the stent into a coronary artery, the stent having a plurality of zig-zag segments, the zig-zag segments capable of being expanded by the balloon; and

(b) a plurality of longitudinally undulating sections of a generally curved shape positioned between and connection the zig-zag segments, wherein the plurality of longitudinally undulating sections can expand and contract in length while being passed through a curved coronary artery.

('370 patent, col. 6, lns. 37-49)

The court construed disputed terms of the '312 and '370 patents as follows:

(1) **"Undulating."** Rising and falling in waves, thus having at least a crest and a trough.

(2) **"Longitudinals" and "longitudinal structures."** Structures that extend or run lengthwise, in the direction of the stent's

longitudinal axis. Although there is no requirement that the longitudinals or longitudinal structures extend the entire length of the stent, the structures have to extend long enough to be considered continuous across a number of points of support.

(3) **"Closed perimeter cells."** A relatively small area on the perimeter of the stent that is bounded on all sides by continuous metal. The word "close" means to block or shut off entry or passage. The word "perimeter" means the boundary of a closed plane figure; outer limits.

(4) **"Zig-zag segments."** A portion of a stent that has one or more short sharp turns or angles.

(5) **"Stent"** or **"stent structure."** A device used to support, expand or hold open an artery or other body passageway.

(D.I. 1116; *D.I. 154[4])

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4. Docket item numbers designated with an asterisk refer to documents filed in Civil Action No. 98-197-SLR.

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C. The Accused Devices

1. AVE's MicroStent II, GFX and GFX2 Stents

The stents manufactured by AVE at issue in this case include the MicroStent II, GFX, and GFX2 stents (the "AVE stents").[5] The AVE stents consist of multiple sinusoidal segments fused together to form a continuously connected device. Each sinusoidal segment is made from a torus, a circular-shaped object that has a circular cross-sectional shape, similar to a doughnut. AVE refers to these tori as "rings." After undergoing a heating process, the rings are bent from their normal configuration into a sinusoidal design characterized by a series of peaks and valleys called "crowns" interconnected by substantially straight portions called "struts." The segments are connected by fusing adjacent crowns together while the segments are positioned end to end in a helical arrangement. The crowns are fused to form a joint or weld using AVE's proprietary autogenous laser fusion process, which melts and fuses existing material from the two crowns so as to ultimately decrease the distance between them. Although it is still possible to identify the fused region using high magnification, there are no discrete sides, facets, faces, or other recognizable geometric features to the fused

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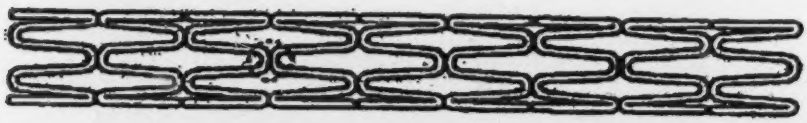
5. Although Cordis alleged that AVE's MicroStent I also infringed the asserted patent claims, that question was not submitted to the jury because the court determined that Cordis had not presented sufficient evidence on the issue during trial. (D.I. 965 at 2202-03; D.I. 966 at 2275-86)

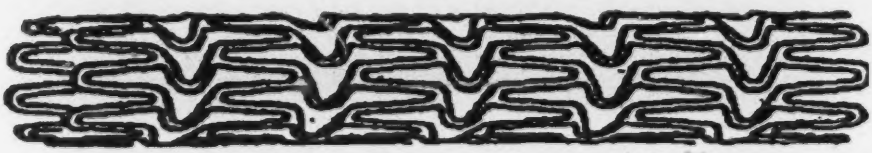
joints, which have a generally hourglass shape. There is only one weld between adjacent segments. The following is a drawing of an AVE stent with one of its welds circled:



The segments of the MicroStent II have four upper and lower crowns and are 3 mm in length. The segments of the GFX and GFX2 have six upper and lower crowns and are 2 mm in length. The AVE stents are constructed in a variety of sizes and lengths, created by connecting a number of individual 3 mm MicroStent II or 2 mm GFX segments together. They are no longer manufactured by AVE. (D.I. 296 at 3-9)

2. BSC's NIR Stent

The NIR stent is the only stent manufactured by BSC that is at issue in this litigation. It is manufactured from a flat sheet of metal upon which a design is etched. The sheet is then rolled into a cylindrical shape and the ends welded together, resulting in a stent composed of segments connected by U-shaped structures. (*D.I. 201 at 1924-27) A drawing of the NIR stent appears below.



D. The Trial

On November 6, 2000, the court commenced a seven-week jury trial in this case, with two separate juries (the "AVE jury" and the "BSC jury"), in four separate phases, per the parties' request.[6] In the first phase of the trial, the AVE jury determined whether the AVE stents infringed the asserted patent claims. In the second phase, the BSC jury determined whether BSC's NIR stent infringed the asserted patent claims. After reaching a verdict regarding BSC's liability, the BSC jury determined damages owed by BSC. Finally, the AVE jury returned after a three-week hiatus to determine damages owed by AVE.[7]

On November 21, 2000, the AVE jury returned a verdict finding that the AVE stents infringed claims 23, 51 and 54 of the '762 patent and claims 1 and 3 of the '984 patent under the doctrine of equivalents.[8] (D.I. 955)

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6. The court will refer to the portion of the trial against AVE as the "AVE trial" and the portion of the trial against BSC as the "BSC trial."

7. The parties requested a "double bifurcation" of the trial to assist the lost profits damages analysis. To receive lost profits, a patentee must prove an absence of non-infringing alternatives. *See Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed.Cir.1995) (en banc) (citing *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir.1978)). Thus, Cordis' ability to present a claim for lost profits in either case was contingent upon first receiving verdicts of infringement in both cases.

8. Neither the jury charge nor the verdict form in the AVE trial distinguished between literal infringement and infringement

(Cont'd)

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The AVE jury also found that the above claims were not invalid for failure to comply with the written description requirement. (*Id.*) On December 22, 2000, the AVE jury awarded Cordis $271,075,085 in damages, including $192,800,460 in lost profits, $77,274,625 based on a 25% reasonable royalty for domestic sales of stents, and a $1,000,000 payment for foreign sales of stents made in the United States. (D.I. 1013)

On December 11, 2000, the BSC jury returned the following verdict regarding the liability of BSC over its NIR stent:

> (1) Claim 23 of the '762 patent: no literal infringement; infringement under the doctrine of equivalents.
>
> (2) Claim 44 of the '762 patent: contributory infringement; invalid pursuant to 35 U.S.C. § 305.
>
> (3) Claim 22 of the '332 patent: no literal infringement; no infringement under the doctrine of equivalents; invalid for obviousness; not invalid for failure to comply with the written description requirement.

(Cont'd)

under the doctrine of equivalents because the court previously granted AVE's motion for summary judgment of no literal infringement. The jury was given a general instruction on "infringement" which mirrored a doctrine of equivalents instruction.

(4) Claim 21 of the '312 patent: no literal infringement;[9] not invalid for obviousness; not invalid for failure to comply with the written description requirement.

(5) Claim 25 of the '370 patent: literal infringement, but no infringement by the reverse doctrine of equivalents; not invalid for failure to comply with the written description requirement.

(6) Claim 26 of the '370 patent: literal infringement, but no infringement by the reverse doctrine of equivalents; invalid for failure to comply with the written description requirement.

(*D.I. 182) On December 15, 2000, the BSC jury awarded Cordis $324,403,250 in damages, including $253,595,750 in lost profits and $70,807,500 based on a 20% reasonable royalty rate. (*D.I. 189)

On February 7, 2001, the court commenced a four-day bench trial on the issue of unenforceability. The court's findings of fact and conclusions of law are rendered in the instant opinion.

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9. Cordis did not assert infringement under the doctrine of equivalents on this claim.

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III. STANDARDS OF REVIEW

A. Motion for Judgment as a Matter of Law

To prevail on a renewed motion for judgment as a matter of law following a jury trial, the moving party " 'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied [by] the jury's verdict cannot in law be supported by those findings.' " *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed.Cir.1998) (quoting *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed.Cir.1984)). " 'Substantial' evidence is such relevant evidence from the record taken as a whole as might be acceptable by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp.*, 732 F.2d at 893. In assessing the sufficiency of the evidence, the court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor, and in general, view the record in the light most favorable to him." *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir.1991); *Perkin-Elmer Corp.*, 732 F.2d at 893. The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." *Perkin-Elmer Corp.*, 732 F.2d at 893. In sum, the court must determine whether the evidence reasonably supports the jury's verdict. *See Dawn Equip. Co. v. Ky. Farms Inc.*, 140 F.3d 1009, 1014 (Fed.Cir.1998).

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B. Motion for a New Trial

Federal Rule of Civil Procedure 59(a) provides, in pertinent part:

> A new trial may be granted to all or any of the parties and on all or part of the issues in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States.

Fed.R.Civ.P. 59(a). The decision to grant or deny a new trial is within the sound discretion of the trial court and, unlike the standard for determining judgment as a matter of law, the court need not view the evidence in the light most favorable to the verdict winner. *See Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36, 101 S.Ct. 188, 66 L.Ed.2d 193 (1980); *Olefins Trading, Inc. v. Han Yang Chem. Corp.*, 9 F.3d 282 (3d Cir.1993); *LifeScan Inc. v. Home Diagnostics, Inc.*, 103 F.Supp.2d 345, 350 (D.Del.2000), *aff'd per curiam*, 13 Fed.Appx. 940 (2001) (citations omitted). Among the most common reasons for granting a new trial are: (1) the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) newly-discovered evidence exists that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the court unfairly influenced the verdict; or (4) the jury's verdict was facially inconsistent. *See Zarow-Smith v. N.J. Transit Rail Operations*, 953 F.Supp. 581, 584 (D.N.J.1997) (citations omitted). The

court must proceed cautiously, mindful that it must not substitute its own judgment of the facts and the credibility of the witnesses for those of the jury. The court should grant a new trial on the basis that the verdict was against the weight of the evidence only where a miscarriage of justice would result if the verdict were to stand. *See Williamson*, 926 F.2d at 1352; *EEOC v. Del. Dep't of Health and Soc. Servs.*, 865 F.2d 1408, 1413 (3d Cir.1989).

IV. CORDIS' STANDING TO SUE

In yet another challenge to Cordis' standing to sue, AVE and BSC argue that Ethicon NJ, a former exclusive licensee to the patents in suit, did not validly transfer its exclusive license to Technicare/Ethicon Ohio, a company with which it merged. This break in the chain of title, according to AVE and BSC, left Cordis with no right to sue on the patents. The court examined the corporate transactions that led to Cordis' license when it denied in part and granted in part ACS's motion to dismiss for lack of standing.[10] (D.I. 162) The court

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10. The court offered the following reasoning for its decision:

> The fact that the licensor may not have given its "express written consent" at the time of each corporate transformation is of no moment, where the parties' course of conduct over the years has been consistent with the licensor's knowledge and approval of the series of assignments.

(D.I. 162 at 4-5)

declines to repeat this exercise, and maintains that Cordis was assigned an exclusive license to the patents at the time the complaint was filed.

V. INFRINGEMENT, INVALIDITY AND DAMAGES[11]

A. Infringement and Invalidity — AVE Trial

1. Infringement of Claims 23, 51 and 54 of the '762 Patent

A determination of infringement requires a two-step analysis. First, the court must construe the asserted claims so as to ascertain their meaning and scope. Second, the claims as construed are compared to the accused product. *See KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1355 (Fed.Cir.2000). Claim construction is a question of law while infringement is a question of fact. *See id.* To establish literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed.Cir.1995). An accused product that does not literally infringe a claim may still infringe under the doctrine of equivalents if each limitation of the claim is met in the accused product either literally or equivalently. *See Sextant Avionique*,

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11. Throughout their briefs, the parties make numerous arguments challenging the court's construction of various terms in the asserted claims. The court went through the claim construction exercise on multiple occasions during the course of these protracted proceedings and declines to readdress its conclusions on claim construction in this opinion.

S.A. v. Analog Devices, Inc., 172 F.3d 817, 826 (Fed.Cir.1999). An element in an accused product is equivalent to a claim limitation if the differences between the two are "insubstantial" to one of ordinary skill in the art. *KCJ Corp.*, 223 F.3d at 1359. A fact finder may also determine equivalence by assessing whether an element "does substantially the same thing in substantially the same way to get substantially the same result" as a claim limitation. *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1260 (Fed.Cir.1989).

Occasionally, "the issue of literal infringement may be resolved with the step of claim construction, for upon correct claim construction, it may be apparent whether the accused device is within the claims." *Multiform Desiccants, Inc. v. Medzam*, 133 F.3d 1473, 1476 (Fed.Cir.1998). Similarly, the determination of infringement under the doctrine of equivalents may be limited as a matter of law. For example, a finding of infringement under the doctrine of equivalents is barred if a claim was amended during prosecution to overcome the prior art. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 585 (Fed.Cir.2000) (en banc), *cert. granted*, 533 U.S. 915, 121 S.Ct. 2519, 150 L.Ed.2d 692, 69 U.S.L.W. 3673 (U.S. June 18, 2001) (No. 00-1543). The scope of equivalents may also be limited by statements in the specification or prosecution history that disclaim coverage of certain subject matter. *See Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1377 (Fed.Cir.1999); *Daum Equip.*, 140 F.3d at 1016.

In the case at bar, the court granted AVE's motion for summary judgment of no literal infringement of claim 23 of the '762 patent by the AVE stents because they did not literally meet the "plurality of slots formed therein" limitation.[12] AVE now challenges the jury's finding that the AVE stents met that limitation by equivalence, arguing that the addition of the "formed therein" language to claim 13 of the '762 patent constitutes a narrowing amendment to the '009 application which bars Cordis from asserting the doctrine of equivalents on claim 23 under *Festo*.

In discussing the relationship between the doctrine of equivalents and prosecution history estoppel, the Federal Circuit in *Festo* ascribed to the doctrine of equivalents the purpose of "prevent[ing] an accused infringer from avoiding liability for infringement by changing only minor or insubstantial details of a claimed invention while retaining the invention's essential identity." *Festo*, 234 F.3d at 564. Prosecution history estoppel, on the other hand, is an equitable tool "that prevents the doctrine of equivalents from vitiating the notice function of claims." *Id.* More specifically, " '[p]rosecution history estoppel precludes a patentee from obtaining under the doctrine of equivalents

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12. The '762 reexamination certificate, which added claims 51 and 54, issued after AVE filed its motion for summary judgment of no literal infringement of claim 23. Because the limitation "plurality of slots formed therein" is also present in claims 51 and 54, the court holds that its finding of no literal infringement of claim 23 by the AVE stents is also applicable to claims 51 and 54.

coverage of subject matter that has been relinquished during the prosecution of its patent application.' " *Id.* (quoting *Pharmacia & Upjohn Co.*, 170 F.3d at 1376-77). "The standard for determining whether particular subject matter was relinquished is an objective one that depends on what a competitor reasonably would conclude from the patent's prosecution history." *Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co.*, 66 F.3d 285, 291 (Fed.Cir.1995). In this regard, "[t]he prosecution history must be examined as a whole."[13] *Id.*

Original claim 19 of the '009 application, the precursor to claim 13 of the '762 patent, is a relatively broad claim, covering both the woven wire mesh and slotted tube embodiments of the "expandable intraluminal graft" first introduced by the '665 patent. The claim reads in relevant part:[14]

> [A] **tubular shaped member having** first and second ends and **a wall surface** disposed between the first and second ends, **the wall surface being formed by a plurality of intersecting elongate members**, at least some of the elongate members intersecting

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13. Because "[t]he application of prosecution history estoppel is a question of law," *LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 867 F.2d 1572, 1576 (Fed.Cir.1989), the issue was not presented to the jury but was preserved for post-trial review.

14. Claims 13 and 18 of the '665 patent as it issued in March 1988 mirror this same language.

> with one another intermediate the first and second ends of the tubular member . . .

(PX 10 at 2353-54) (emphasis added)

As explained in greater detail in the court's claim construction analysis, claim 13 of the '762 patent is narrower in scope, describing only one of the embodiments covered by the '665 patent, that is, the slotted tube embodiment. Claim 13 requires

> **a thin-walled tubular member having** first and second ends and **a wall surface** disposed between the first and second ends, **the wall surface having** a substantially uniform thickness and a **plurality of slots formed therein** . . .

('762 patent, col. 11, lns. 64-68) (emphasis added) The court opined that, unlike the tubular member of the '665 patent whose wall surface is formed by "intersecting elongate members," the tubular member claimed by the '762 patent starts with a wall surface and the elongate members are formed by removing material from the wall surface (to wit, "slots [are] formed therein"). (D.I. 464 at 10-17)

In light of this background, it is the court's conclusion that Cordis is not entitled to the protection of the doctrine of equivalents with respect to tubular members that do not have a pre-existing wall surface, such as the AVE stents. The patentee at bar chose to

more narrowly define his invention in the '762 patent by emphasizing a specific feature of the balloon expandable intraluminal graft—a pre-existing wall surface that was required to have certain characteristics, i.e., "thin-walled," the wall surface having a "substantially uniform thickness," and "a plurality of slots formed therein." The notice function of patent claims would be ill served if this court were to allow Cordis, under the guise of equivalency, to embrace within the scope of the '762 patent stents lacking the very feature that distinguishes the '762 patent from the broader '665 patent. A competitor reviewing the development of Dr. Palmaz's slotted tube invention reasonably would conclude that a tubular member whose wall surface is formed by bending wire does not fall within the scope of claim 23 of the '762 patent. Therefore, the range of equivalents sought by Cordis is barred by the prosecution history of the '762 patent and the jury's verdict of infringement under the doctrine of equivalents is reversed.

2. Invalidity of Claims 23, 51 and 54 of the '762 Patent

AVE challenges the jury's verdict that the asserted claims of the '762 patent are not invalid for failure to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1, which provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such

> full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1.

Patent claims are presumed valid. *See* 35 U.S.C. § 282. *See also Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1054 (Fed.Cir.1989) ("The presumption of validity under 35 U.S.C. § 282 carries with it a presumption the examiner did his duty and knew what claims he was allowing."). To overcome this presumption, AVE was required to "provide clear and convincing evidence that persons skilled in the art would not recognize in the disclosure a description of the claimed invention." *Biacore v. Thermo Bioanalysis Corp.*, 79 F.Supp.2d 422, 467 (D.Del.1999), *aff'd per curiam*, 30 Fed.Appx. 994 (2002).

AVE contends that Cordis' use of the "building block" theory during trial renders claims 23, 51 and 54 of the asserted claims of the '762 patent invalid for failure to comply with the written description requirement. The "building block," shown below, is essentially a severed portion of Figure 1A of the '762 patent, resembling a completely half-slotted stent.

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AVE argues that the specification of the '762 patent fails to contemplate an all half-slotted stent and, therefore, the court should either find the asserted claims invalid as a matter of law, or clarify the definition of "plurality of slots" to require at least one complete slot.

The court has declined over the course of these proceedings to limit the word "slot" to a long and narrow opening that is completely surrounded by material (i.e., a closed or complete slot), based on the ordinary meaning of the word (e.g., the "slots" of a comb) and the fact that each of Dr. Palmaz's tubular structures had to have open or half-slots in order to expand. The tension between adequate disclosure of the scope of an invention and construing claims more broadly than the preferred embodiment has permeated the litigation at bar. The court declines to revisit the question. AVE's

motion for judgment as a matter of law on this issue is denied.[15]

3. Infringement of Claims 1 and 3 of the '984 Patent

Prior to trial, the court granted AVE's motion for no literal infringement of claims 1 and 3 of the '984 patent because the AVE stents did not literally contain the "plurality of slots formed therein" limitation. (D.I. 462) AVE now challenges the jury's finding that its stents infringed claims 1 and 3 under the doctrine of equivalents because of arguments made by the patentee during prosecution of the '984 patent to distinguish two prior art references: United States Patent No. 4,969,458 ("Wiktor") and the Gianturco Connected Z-Stent disclosed in an article by Tetsuya Yoshioka, *et al.*, entitled, "Self-Expanding Endovascular Graft: An Experimental Study in Dogs," published in the *American Journal of Roentgenology* in October 1988 ("Yoshioka"). (AVEX 438) The "bent wire" stents disclosed by Wiktor and Yoshioka are reproduced below.

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15. To the extent that AVE argues that claims 1 and 3 of the '984 patent are invalid for failing to satisfy the written description requirement, the court maintains that this defense was never a part of the case, and AVE is barred from raising it at this time. (D.I. 963 at 1365)

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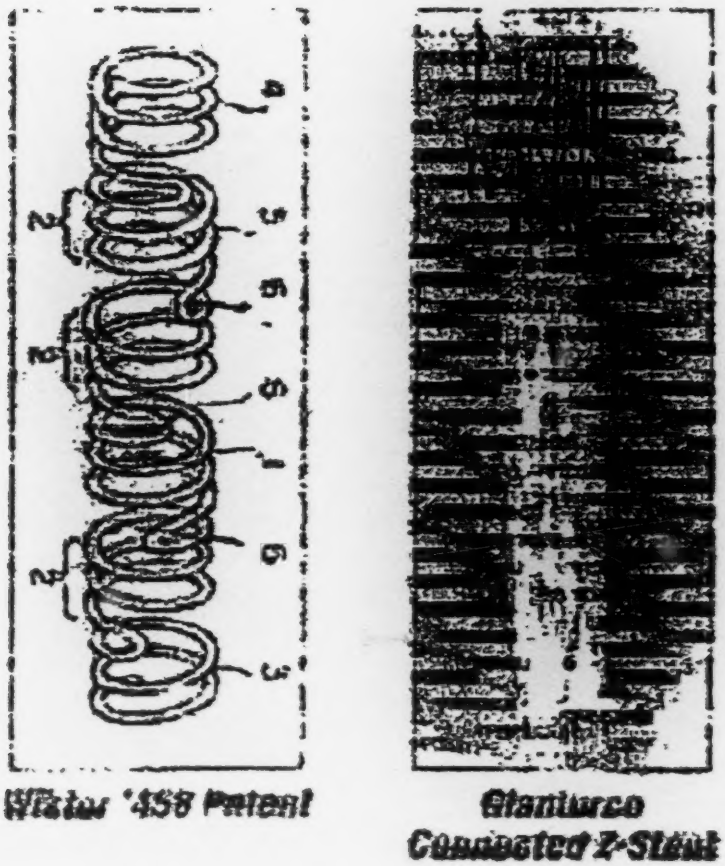

In arguing that "Wiktor is simply not responsive to the claimed structural limitations of [c]laims 1 and 4," the patentee explained that

> Wiktor does not disclose a plurality of "thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall

> surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member." Wiktor discloses a single stent, or graft made up of coiled wire. **There is no wall surface having a plurality of slots**, nor slots disposed parallel to the longitudinal axis of each tubular member.

(PX 16, Tab 49 at 631) (emphasis added) A reasonable interpretation of this declaration is that the patentee surrendered bent wire stents, as AVE argues.

Such an interpretation is consistent with the prosecution history of the '984 patent, which is replete with references to the '665 and '762 patents, describing such prior art as disclosing

> expandable intraluminal grafts and methods and apparatus for implanting expandable intraluminal grafts which may be used in practicing the present invention. These three patents are commonly owned with the present application.

(PX 16, Tab 19 at 509; *see also id.*, Tab 22 at 518) The above statement reflects the fact that the '665, '762 and '984 patents, among others, share essentially the same specification and the '984 patent claims the same basic structure (albeit in multiples) in the same language as does the '762 patent, to wit:

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> [A] plurality of **thin-walled tubular members**, each **having** first and second ends and **a wall surface** disposed between the first and second ends, **the wall surface having** a substantially uniform thickness and a **plurality of slots formed therein**, the slots being disposed substantially parallel to the longitudinal axis of each tubular member.

('984 patent, claims 1 and 4, col. 11, lns. 46-52; col. 12, lns. 25-31) (emphasis added) Given the common history of the '762 and '984 patents, this court construed common claim limitations consistently. Having found that the patentee of the '762 patent surrendered structures that have no pre-existing wall surface, it would be inequitable to find otherwise in connection with the '984 patent.

Therefore, Cordis is barred from asserting infringement of claims 1 and 3 of the '984 patent under the doctrine of equivalents. This conclusion is based upon the patentee's concession that Wiktor, a bent wire stent, does not disclose a "wall surface having a plurality of slots," as well as the common history of the '762 and '984 patents.

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B. Infringement and Invalidity—BSC Trial

1. Infringement of Claim 23 of the '762 Patent

The jury determined that BSC's NIR stent infringes claim 23 of the '762 patent under the doctrine of equivalents. BSC contends that prosecution history estoppel narrows or bars the application of the doctrine of equivalents to the "substantially uniform thickness," "wall surface" and "smooth surface" limitations of claim 23, and that there was insufficient evidence to find that the NIR stent literally met any of those limitations. Because the jury was not given a detailed verdict form, the court must uphold the verdict only if it there was sufficient evidence to support a finding that the NIR stent meets one or more limitations by equivalence, and every other limitation literally. *See, e.g., Comark*, 156 F.3d at 1188. The court concludes that, although prosecution history estoppel bars the application of the doctrine of equivalents to the "substantially uniform thickness" limitation, Cordis presented substantial evidence to support a finding that the NIR stent contains that limitation literally, and contains the "wall surface" and "smooth surface" limitations under the doctrine of equivalents. Thus, BSC's motion for judgment as a matter of law that claim 23 of the '762 patent is not infringed by the NIR stent is denied.[16]

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16. BSC also makes several arguments that Cordis is barred from asserting infringement of claim 23 under the doctrine of equivalents based on *Festo* and *Intermatic, Inc. v.* (Cont'd)

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a. "Substantially Uniform Thickness"

BSC contends that the patentee's efforts to distinguish United States Patent No. 3,657,744 ("Ersek") during reexamination of the '762 patent estops Cordis from asserting the doctrine of equivalents on the "substantially uniform thickness" limitation of claim 23. Ersek discloses a tubular structure that is manufactured by cutting openings in a flat sheet of metal, pulling the sheet to expand the openings, and then rolling the sheet into a cylindrical shape and welding it together. Expanding the openings causes the struts of the resulting metal tube to be twisted, enabling the structure to become embedded in tissue upon surgical implantation. (BSCX 6228, col. 2, ln. 56 - col. 3, ln. 9) Figures 2 and 5 of Ersek are shown below.

(Cont'd)

Lamson & Sessions Co., 273 F.3d 1355 (Fed.Cir.2001). First, BSC argues that the addition of the terms "smooth surface" and "substantially uniform thickness" to claims 35 and 37 during reexamination bars the application of the doctrine of equivalents to claim 23, which also contains those limitations. Second, BSC claims that Cordis is estopped from asserting equivalence on the "smooth surface" limitation because of the cancellation of claim 13, from which claim 23 depends. Finally, BSC contends that *Festo* applies to argument-based estoppel as well as amendment-based estoppel. Because this court concludes that Cordis presented substantial evidence to support a finding that the NIR stent **literally** contains these limitations, and in light of the present review of *Festo* by the United States Supreme Court, this court declines to further address BSC's arguments.

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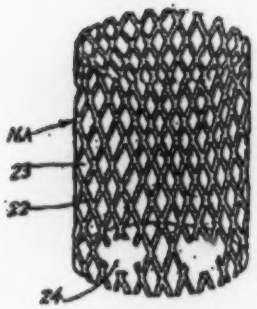

FIG. 2

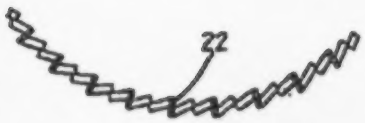

FIG. 5

During reexamination, the patentee stated the following to distinguish Ersek from the claims of the '762 patent:

> As shown therein and in Ersek Figure 5, in the first diameter configuration, the wall of sleeve 16 is of varying thickness because the strands of the sleeve have twisted out of the plane of the starting material. Moreover, the bonds or bridges at the junctions of the strands protrude inwardly and outwardly of the plane of the starting material, and as a result the Ersek sleeve 16 has a non-uniform wall of varying thickness.

(PX 13 at 3049) The patentee also cited the "Antonsson Affidavit," which stated that Ersek's wall thickness "ranged from a minimum thickness of 0.0035 inches to a maximum thickness of 0.0045 inches." (PX 13 at 3050-51) The court integrated the patentee's arguments into its construction of the "substantially uniform thickness" limitation:

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> The thickness at all points along the wall surface of the tubular member, both at its first and second diameters, must be substantially the same. **Variances as little as .001 inches fall outside the scope of "substantially uniform."**

(D.I. 790, 1116) (emphasis added)

BSC contends that Cordis is estopped from claiming equivalence of any accused device that has a variance in wall thickness of 0.001 inches or more. Having incorporated the patentee's arguments distinguishing Ersek into its claim construction, the court is now confronted with the often puzzling task of determining where claim construction ends and prosecution history estoppel begins. Under the reasoning employed in *Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106 (Fed.Cir.2000), *cert. denied*, 532 U.S. 1008, 121 S.Ct. 1734, 149 L.Ed.2d 659 (2001), however, the court concludes that the term "substantially uniform" is not entitled to a scope of equivalents. First, consistent with the court's construction that a wall surface with a "substantially uniform thickness" must not vary more that .001 inches, to characterize as equivalent what is by definition not of a "substantially uniform thickness" would be to vitiate the limitation. Second, "it would defy logic to conclude that" a wall surface without a substantially uniform thickness "could be insubstantially different from a claim limitation requiring" a substantially uniform thickness, "and no reasonable juror could find otherwise." *Id.* Thus, as a matter of law,

Cordis is estopped from claiming equivalence of any accused product whose wall surface varies in thickness by 0.001 inches or more.[17]

Nevertheless, the court finds that Cordis presented substantial evidence at trial to support a finding that the NIR stent literally contains the "substantially uniform thickness" limitation. Drs. Buller and Collins relied on engineering drawings of the NIR stent to show that the thickness of its struts varies by only .0004 inches, which is within the court's definition. (*D.I. 197 at 757-58; *D.I. 198 at 1202; PX 3776) They also relied on a weld grind elimination report to show that about 25% of the welds on the NIR stent do not vary in thickness by more than 0.001 inches. (*D.I. 197 at 758-61, 932-33, 938-40; *D.I. 198 at 1198-99, 1202-04; PX 3745) Because the jury was entitled to accept Cordis' theory of individual tubular members serving as a basis for the infringement analysis, and each tubular member of the NIR stent contains one weld (*D.I. 198 at 1194), the jury reasonably concluded that the NIR stent literally contains the "substantially uniform thickness" limitation of claim 23.

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17. Cordis' contention that Ersek does not have a "substantially uniform thickness" because its tubular structure has areas that are several times the thickness of the starting material is misplaced. That argument was used to distinguish Ersek from the "thin-walled" limitation contained in certain claims of the '762 patent. (PX 13 at 3054-55)

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b. "Smooth Surface"

BSC also argues that the patentee's efforts to distinguish Ersek during reexamination of the '762 patent estop Cordis from asserting the doctrine of equivalents on the "smooth surface" limitation. During reexamination, the patentee stated:

> A clear purpose of Dr. Palmaz's invention is to provide a low-profile, small diameter product that is **smooth enough that it can be intraluminally delivered** from a remote location to a desired location without the risk of damaging the body passageway.

(PX 13 at 3053) (emphasis added) Based on this argument, Cordis advocated a functional definition of "smooth surface"—that the surface be smooth enough for intraluminal delivery. The court determined, however, that the patent claims suggested a narrower structural definition. Claim 13 requires a "tubular member having a first diameter **which permits intraluminal delivery** of the tubular member into a body passageway having a lumen," whereas claim 23 requires that the "outside of the wall surface of the tubular member is a **smooth surface**, when the tubular member has the first diameter." Thus, the inclusion of "smooth surface" in dependent claim 23 suggests that the term must mean more than simply "suitable for intraluminal delivery." The court adopted a dictionary definition of "smooth," also mentioned by the patentee in distinguishing Ersek from the '762 patent:

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> The outside of the wall surface of the unexpanded tubular member has a continuously even surface, without roughness, points, bumps or ridges, especially to the touch.

(D.I. 790, 1116; PX 13 at 003049-50) Because the court incorporated the patentee's arguments distinguishing Ersek into a structural definition of "smooth surface" and finds no reason in the prosecution history to preclude a finding of equivalence, prosecution history estoppel does not narrow the doctrine of equivalents on this limitation.

Furthermore, the court finds that there was substantial evidence presented at trial to support a verdict that the NIR stent contains the "smooth surface" limitation either literally or under the doctrine of equivalents. Dr. Buller testified that the NIR stent has a "smooth surface," and an article by Dr. Kobi Richter in the *Handbook of Coronary Stents* describes the NIR stent as having a "smooth surface." (*D.I. 197 at 766-68; *D.I. 200 at 1669; PX 275 at 134) Furthermore, the jury was given the opportunity to handle the NIR stent and determine if it was "without roughness, points, bumps or ridges, especially to the touch." (*D.I. 199 at 1533) In sum, Cordis presented substantial evidence to support the jury's verdict and BSC's motion for judgment as a matter of law on this issue is denied.

c. "Wall Surface"

Finally, BSC contends that Cordis is estopped from asserting the doctrine of equivalents on the "wall surface" limitation of claim 23. The patentee distinguished Ersek as not having a "wall surface disposed between the first and second ends" because the wall of the stent was not "disposed in a common cylindrical plane:"

> As is evident from the specification of the '762 patent, with particular reference to Figure 1A, the connecting members and elongate members that collectively form the tubular member 71 have an outer surface that is disposed in a common cylindrical plane. No comparable wall surface is present in Ersek's fixation sleeve, and it would render Ersek inoperable for its intended purpose to modify sleeve 16 and eliminate the outwardly projecting edges, since the thus modified sleeve would eliminate the very structure contemplated by Ersek for retaining the associated graft or heart valve within the body passageway.

(PX 13 at 3054) Again, the court incorporated the patentee's prosecution arguments into its claim construction when it defined "wall surface" to require that the "outer surface of the tubular member must be disposed in a common cylindrical plane." The court finds no evidence in the prosecution history to preclude a

finding of equivalence based on this definition, thus, Cordis is not estopped from asserting the doctrine of equivalents on this limitation.

The court also finds that substantial evidence supports a finding that the NIR stent contains a "wall surface," either literally or under the doctrine of equivalents. Dr. Buller stated that the "tubular members of the NIR stent are disposed in a cylindrical shape ... [i]t fulfills exactly that claim language," and that the welds lie in the same plane as the tubular members. (*D.I. 197 at 754-55) Dr. Collins also testified that the NIR stent's wall surface, including the welds, lies in a common cylindrical plane. (*D.I. 198 at 1201) In sum, the court finds that there is sufficient evidence in the record to support the jury's verdict.[18]

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18. BSC's motion for a new trial to consider the reverse doctrine of equivalents for claims determined to be infringed under the doctrine of equivalents is denied. *See Martin v. Barber*, 755 F.2d 1564, 1567 n. 1 (Fed.Cir.1985) ("[The reverse doctrine of equivalents] becomes an issue only when the accused device falls within the literal words of a claim."). BSC's motion for a new trial to determine if the NIR stent infringes claim 23 under the doctrine of equivalents because the jury's verdict was against the weight of the evidence is also denied.

2. Contributory Infringement of Claim 44 of the '762 Patent

BSC argues that it is entitled to judgment as a matter of law that claim 44 of the '762 patent is not infringed or, in the alternative, to a new trial, for three reasons: (1) there is no predicate act of direct infringement by any one entity or related entities; (2) the NIR stent is suitable for substantial noninfringing use; and (3) Cordis failed to prove that BSC had the requisite knowledge for contributory infringement.

Pursuant to 35 U.S.C. § 271(c),

> [w]hoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

There can be no contributory infringement in the absence of direct infringement. *See Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341-42, 81 S.Ct. 599, 5 L.Ed.2d 592 (1961). Furthermore, "only proof of a defendant's knowledge, not intent, that his activity cause[s] infringement [is] necessary to establish contributory infringement." *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1469 (Fed.Cir.1990).

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a. Predicate Act of Direct Infringement

To constitute a predicate act of direct infringement of a process claim, either a single entity must perform every step of the method or, if two or more entities perform different steps of the method, those entities must have some connection to each other. *See, e.g., Faroudja Labs., Inc. v. Dwin Elecs., Inc.*, No. 97-20010, 1999 WL 111788, at *5 (N.D.Cal. Feb.24, 1999) ("It is true that several district courts have found a party liable for direct infringement of a process patent even where the various steps included in the patent are performed by distinct entities. However, these cases indicate that some connection between the different entities justified that finding.").[19]

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19. During the jury charge conference, BSC argued that a higher standard is required to establish contributory infringement by related entities, one in which the entities must "work in concert," "work together jointly" or have an "agency" relationship. The court rejected these arguments and instead adopted the "some connection" standard used in the *Faroudja* case:

> Cordis must prove by a preponderance of the evidence each of the following to establish contributory infringement of claim 44, which covers a method of medical treatment: . . .
>
> 5. That every step of the method of medical treatment described in claim 44 is performed either by a single entity, or by different persons or entities who have **some connection** to each other.

(D.I. 1116) (emphasis added) BSC now presents no arguments that compel the court to change its prior decision.

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BSC argues that, although physicians who implant NIR stents in coronary arteries may carry out some of the first, third, fourth and fifth steps of the method of claim 44—utilizing, inserting, delivering and expanding the NIR stent, respectively—they do not carry out the second step of "disposing" the NIR stent on a balloon catheter. Rather, BSC performs this step by selling the NIR stent in the United States premounted on a catheter, and BSC has no relationship to physicians who perform the other steps.

The court finds that there was sufficient evidence presented at trial to support the finding of the jury that BSC has "some connection" to physicians who implant the NIR stent. For instance, Dr. Buller testified about the relationship between BSC and the medical community:

> There's a very close relationship. I think you heard evidence of the close relationship between Boston Scientific and its personnel and the doctors, and we, in all countries, in Europe as well, depend very much on industry for this relationship, for teaching us about new products, how to use them, when they're appropriate to be used and generally how the products perform and how they might benefit our patients.

(*D.I. 203 at 2549) He also testified that BSC supplies samples of the NIR stent to physicians, and recruits physicians to participate in clinical trials. (*Id.*)

BSC's chairman, Peter Nicholas, also testified about BSC's close relationship with physicians:

> Well, we have a network of thousands of people in the field. These are professional salespeople in the field all throughout the world. And they're talking to physicians every day. I think we talked to perhaps five, ten thousand physicians every single day with our organization. And we selected a handful, maybe 15 to 20 of those physicians throughout the world who are, in our view, really leaders in the world. And we asked them to tell us about the NIR stent.

(*D.I. 199 at 1457) Thus, BSC's motion for judgment as a matter of law or a new trial on this issue is denied.

b. NIR Stent as a Staple Article of Commerce Suitable for Substantial Noninfringing Use

BSC also challenges the jury's finding that the NIR stent is incapable of "substantial noninfringing uses." The court instructed the jury on this issue as follows:

> In determining whether the NIR stent is a "staple article of commerce," you should focus on the NIR stent actually supplied by Boston Scientific, and you should take into account the quality, quantity and efficiency of the suggested uses. That a product is known

> to have potential infringing uses is not sufficient to establish contributory infringement. You should also consider in this regard the uses for which the NIR stent has been approved by the FDA and the labeling and instructions of the NIR stent.

(D.I. 1116)

Although BSC presented evidence that the NIR stent is **suitable** for implantation in body passageways other than the coronary artery,[20] the court finds that the jury reasonably concluded that these uses are not "substantial." *See Hoffmann-LaRoche, Inc. v. Promega Corp.*, 1994 WL 761241 (N.D.Cal.1994) ("Whether a use is 'substantial' or not depends on how likely and often the use will occur. Thus, occasional aberrant use of a product does not make that use 'substantial.' Similarly, inefficient and uneconomical uses are less likely to be deemed 'substantial.' ") (citations omitted). BSC promotes the NIR stent to physicians as a coronary stent, and FDA-approved labeling states that the NIR stent is used only for "improving coronary lumen diameter." (PX 276 at 281; PX 3796A) Dr. Buller, a member of BSC's advisory board when the NIR stent was launched, testified that he was not aware of any

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20. The instructions that accompany the NIR stent state that it may be used to treat lesions in saphenous vein grafts, and the NIR stent has been approved by the FDA for use in the biliary system. (PX 3796A; BSCX 9872; *D.I. 199 at 1464) Also, BSC's expert Dr. David Cumberland testified that the NIR stent is suitable for use in the renal arteries. (*D.I. 200 at 1602)

"substantial" use of the NIR stent outside the coronary arteries. (*D.I. 197 at 781) In sum, the court finds that, based on the evidence presented, the jury reasonably determined that any uses of the NIR stent outside the coronary arteries are not "substantial."

c. BSC's Knowledge

Finally, BSC argues that Cordis failed to show that BSC possesses the requisite knowledge for contributory infringement:

> That BSC sold or supplied the NIR stent with knowledge that the NIR stent was especially made for use in the manner claimed in claim 44 of the '762 patent.

(D.I. 1116) *See Hewlett-Packard*, 909 F.2d at 1469 n. 4 (citing *Aro Mfg.*, 377 U.S. at 488, 84 S.Ct. 1526). The court finds that Cordis presented substantial evidence to support the jury's finding that BSC possessed knowledge that the NIR stent is "especially adapted for a particular use proscribed by a known patent." *Snuba Int'l v. Dolphin World, Inc.*, 2000 WL 961363, at *7 (Fed.Cir.2000). BSC is aware of how the NIR stent is used and instructs physicians in that use. (PX 3796A) BSC's motion for judgment as a matter of law that its lacks the requisite knowledge to establish contributory infringement of claim 44 is denied.

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3. Invalidity of Claim 44 of the '762 Patent

Cordis moves for judgment as a matter of law that claim 44 of the '762 patent is not invalid for failure to comply with 35 U.S.C. § 305. Section 305 provides, in pertinent part:

> In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301 of this title,[21] or in response to a decision adverse to the patentability of a claim of a patent. No proposed amended or new claim enlarging the scope of a claim of the

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21. Section 301 provides:

> Any person at any time may cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent. If the person explains in writing the pertinency and manner of applying such prior art to at least one claim of the patent, the citation of such prior art and the explanation thereof will become a part of the official file of the patent. At the written request of the person citing the prior art, his or her identity will be excluded from the patent file and kept confidential.

35 U.S.C. § 301.

> patent will be permitted in a reexamination proceeding under this chapter.

35 U.S.C. § 305. Cordis argues that: (1) the question of invalidity under § 305 is one for the court and not the jury; and (2) claim 44 was added during reexamination for a proper purpose.

a. Question for the Court or the Jury

The Federal Circuit has characterized invalidity under § 305 as a question of law which it must review *de novo*. *See In re Freeman*, 30 F.3d 1459, 1464 (Fed.Cir.1994) ("Whether amendments enlarge the scope of a claim is a matter of claim construction. Claim construction is a question of law which we review *de novo*.") (citing *In re Donaldson Co., Inc.*, 16 F.3d 1189, 1192 (Fed.Cir.1994)). During the trial, the court reserved decision on whether this issue is one for the court or jury, and allowed the jury to address the issue in the event that the court later determined that it was a jury question. (*D.I. 203 at 2493) Upon careful consideration, the court concludes that, pursuant to the language of the Federal Circuit in *In re Freeman*, invalidity under § 305 is a question for the court and not the jury. Although BSC argues that the specific issue at bar is not "whether amendments enlarge the scope of a claim," but rather, whether a claim was added for a proper purpose, the court finds no persuasive authority requiring a jury to decide such an issue, nor is such an issue an inappropriate question for the court. Contrary to BSC's position, the court may, and is often required

to, address issues with similar factual underpinnings, such as prosecution history estoppel. Thus, the court shall decide the issue of invalidity of claim 44 under § 305, using the jury's verdict as an advisory opinion.

b. Reasons for Addition of Claim 44 in Reexamination

According to § 305, a claim may be added or amended upon reexamination for only two reasons: (1) to distinguish the invention as claimed from the prior art; or (2) in response to a decision adverse to the patentability of a claim of a patent. *See* 35 U.S.C. § 305. *See also In re Freeman*, 30 F.3d at 1468 ("[T]he ability of a patentee to amend claims during reexamination must be seen in light of the fundamental purpose of reexamination—the determination of validity in light of a substantial new question of patentability. Thus, amendment of claims during reexamination is limited to amendment in light of prior art raising a substantial new question of patentability.") (citing *In re Yamamoto*, 740 F.2d 1569, 1572 (Fed.Cir.1984)). Cordis argues that claim 44 was added to the '762 patent for both permissible reasons, whereas BSC contends that claim 44 was added solely to cover the stents of Cordis' competitors.

In October 1997, reexamination of the '762 patent was requested in view of three additional pieces of prior art: Ersek, U.S.S.R. Inventor's Certificate 660689 ("Kononov"), and United States Patent No. 4,787,899 ("Lazarus"). (PX 12 at 1407) In a subsequent office

action, the examiner rejected claims 1-8 and 35-38 as unpatentable under 35 U.S.C. § 103(a) in light of the additional prior art. (PX 13, Tab 32) The patentee then submitted an Amendment on July 21, 1998 that included an amended claim 1 and several additional claims, including claim 44. In its remarks accompanying the Amendment, the patentee stated:

> Claims 1, 13, 24, 35 and 37 have been amended in accordance with the discussions with Examiner Thaler at the above-noted interviews, and in subsequent telephone discussions on July 13, 1998. **Added claims 44-59 are all narrower in scope than the original claims, and provide specific protection for aspects of the disclosed invention which have been incorporated into competitive products and methods.**

(PX 13 at 3045-46) (emphasis added)

The only other mention of claim 44 in the prosecution history appears in the Examiner's Reasons for Allowance dated August 25, 1998. Examiner Thaler remarked:

> Claim 44 is a new claim. This claim includes the step of expanding and deforming the stent prosthesis at an area of stenosis within the coronary artery. This claim is more limited than amended claim 1. It would not have been obvious to locate either the Lazarus or the

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> Kononov device within the coronary artery at the area of stenosis for substantially the same reasons as those [applicable to claim 1].

(PX 14 at 3256-57)

The court finds that claim 44 was added solely to cover competitors' stents, and not for a permissible reason under § 305. The patentee clearly stated that claim 44 was added to provide protection for "aspects of the disclosed invention which have been incorporated into competitive products and methods." Examiner Thaler's remarks about claim 44 pertain to the patentability of claim 44 itself, not how claim 44 enhances the patentability of claim 1. In fact, Examiner Thaler's prior objections to claim 1 were withdrawn not because of claim 44, but because of the insertion of the phrase, "at the location of an existing natural obstruction within the body passageway," into claim 1. (PX 14 at 3254-56) Claim 44 is simply a narrower version of claim 1, and there is no indication in the prosecution history that claim 44 was added to distinguish the invention as claimed from the prior art, or in response to the original rejection of claim 1 for obviousness. Although a patentee may add claims to cover a competitor's product, the addition of those claims must comply with the patent laws. *See Kingsdown Med. Consultants Ltd. v. Hollister, Inc.*, 863 F.2d 867, 874 (Fed.Cir.1988). Because the court finds that claim 44 was not added for a permissible reason under § 305, Cordis' motion for judgment as a matter of law on this issue is denied.

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4. Invalidity of Claim 22 of the '332 Patent

BSC contends that it is entitled to judgment as a matter of law that claim 22 of the '332 patent is invalid for failure to comply with the written description requirement because the specification of the '332 patent fails to disclose multiple connectors. The court finds that the jury reasonably concluded that BSC failed to demonstrate by clear and convincing evidence that claim 22 is invalid. The specification of the '332 patent states that "[t]he present invention includes . . . a single connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members," but never limits the invention to containing **only** single connector members. ('332 patent, col. 3, lns. 38-45) Moreover, because the '332 patent is a continuation of the '984 patent, the jury properly considered the specification and file history of the '984 patent, whose original claims were directed to a stent "**comprising** . . . a single connector member being disposed between adjacent tubular members." (PX 16 at 481-42) The use of the open-ended term "comprising" suggests that multiple connectors may also be present. Furthermore, the prosecution history of the '984 patent contains several references to multiple connectors. (PX 16 at 575-76; PX 17 at 2885) The jury's verdict is consistent with the weight of the evidence, thus, BSC's motion for judgment as a matter of law on this issue is denied.

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5. Infringement of Claims 25 and 26 of the '370 Patent

BSC challenges the jury's finding that the NIR stent literally infringes claims 25 and 26 of the '370 patent. Specifically, BSC contends that Cordis inappropriately altered the parties' and the court's understanding of the term "undulating" and, under the intended construction of the term, the evidence presented at trial does not support a conclusion that the NIR stent contains "undulating" sections.

During claim construction, the parties and the court agreed that the words "crest" and "trough" define arcing curves, not just points at the top or bottom of a curve.[22] With this understanding of the terms, the court defined "undulating" to mean "rising and falling in **waves**, thus having at least a crest and a trough." The use of the plural "waves" implies a change in direction, as suggested by Figure 8 of the '370 patent, shown below.

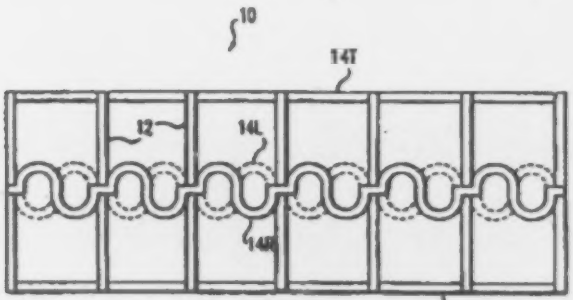

FIG.8

22. The court added the "crest" and "trough" language to address a dispute between the parties about whether "undulating" required both a crest **and** a trough, as opposed to a crest **or** a trough.

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The court did not include the "change in direction" language in the claim construction because neither party suggested it was necessary, as it was contemplated under BSC's definition which was embraced by the court.

At trial, Cordis presented no evidence to suggest that the NIR stent has two arcing curves or waves which can be identified as a crest and a trough. Instead, Cordis argued that the "U" shaped member of the NIR stent represents one full cycle of a sine wave, which includes one crest (the combined two top points of the "U") and one trough (the "U" curve itself). (*D.I. 203 at 2631-33) Cordis' attempt at satisfying the court's claim construction, albeit creative, is unsuccessful. "To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Techs.*, 54 F.3d at 1574. The court finds that Cordis failed to present sufficient evidence to prove that the NIR stent literally contains "undulating" sections as defined by the court. BSC's motion for judgment as a matter of law on this issue is granted. Because the court finds that the NIR stent does not literally infringe claims 25 and 26 of the '370 patent, Cordis' motion for judgment as a matter of law on the reverse doctrine of equivalents is denied as moot.

6. Invalidity of Claim 25 of the '370 Patent and Claim 21 of the '312 Patent

BSC moves for judgment as a matter of law that claim 25 of the '370 patent and claim 21 of the '312 patent are invalid for failure to comply with the written description requirement because the specifications disclose only "ring" stents whereas the claims refer broadly to a "stent" and "stent structure." *See Tronzo v. Biomet*, 156 F.3d 1154, 1158-59 (Fed.Cir.1998) (holding that unless disclosure suggests to one skilled in the art that broader, more generic invention is necessarily part of disclosure, claims directed to broader invention are invalid for failure to comply with written description requirement). *See also Wang Labs., Inc. v. America Online, Inc.*, 197 F.3d 1377, 1383 (Fed.Cir.1999). BSC also argues that the claims are invalid because they fail to claim "rings," which are an essential feature of the invention. *See Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1480 (Fed.Cir.1998) (holding that if patent applicant has made clear that particular feature is essential to underlying invention, that feature may not be omitted from claims without violating written description requirement). *See also Johnson Worldwide Assoc., Inc. v. Zebco Corp.*, 175 F.3d 985, 993 (Fed.Cir.1999).

The court finds that the jury reasonably concluded that the '312 and '370 patent specifications disclose two separate and distinct attributes of a stent - circular rings for radial strength and undulating structures for

longitudinal flexibility. At trial, Dr. Tim Fischell stated that the inventors' goal was two-fold:

> . . . . our basic concepts at the time were to make a stent that would be very strong when expanded . . . . But also, to make a stent that would be very flexible. . . .

(*D.I. 196 at 526-27) Dr. Buller also described the Fischells' invention as follows:

> . . . . their invention was two different things. One component of their invention was trying to go to close to perfectly circular rings, to support the lumen . . . . And the other component of their invention was undulations within longitudinal structures, to actually bring about even better flexibility within the design of a stent.

(*D.I. 197 at 818-19) Furthermore, the specifications describe the benefits of undulating structures in general terms that are applicable to any kind of stent:

> A stent such as stent 10 could have two or more undulating longitudinals. Such a stent would bend more easily during insertion into a vessel and would be more readily adaptable for placement in curved vessels such as some coronary arteries.

(312 patent, col. 3, lns. 45-49; '370 patent, col. 3, lns. 46-50)

Because claims 25 and 21 disclose "undulating" structures which are reasonably considered to be one of two separate features of the invention disclosed by the '312 and '370 patents, BSC's motion for judgment as a matter of law that the claims are invalid for failure to comply with the written description requirement is denied.

C. Damages

Upon a finding of infringement, the patent laws permit an award of damages adequate to compensate the patentee for infringement, but in no event less than a reasonable royalty. *See* 35 U.S.C. § 284. To recover lost profits, "a patent owner must prove a causal relation between the infringement and its loss of profits." *BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1218 (Fed.Cir.1993). In other words, the burden rests on the patentee to show a reasonable probability that "but for" the infringing activity, the patentee would have made the infringer's sales. *Water Tech. Corp. v. Calco Ltd.*, 850 F.2d 660, 671 (Fed.Cir.1988). To prove entitlement to lost profits, the patentee must demonstrate, *inter alia*, an absence of non-infringing alternatives, and that it possessed the marketing capacity to make the lost sales. *See Rite-Hite*, 56 F.3d at 1545 (citing *Panduit*, 575 F.2d at 1156); *SmithKline Diagnostics Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1165 (Fed Cir.1991) (citing *Panduit*, 575 F.2d at 1156). For those infringing sales for which a patentee cannot establish an entitlement to lost profits, damages in the form of a "reasonable royalty" are required.

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A reasonable royalty is the amount that a person desiring to manufacture, use or sell a patented article, as a business proposition, would be willing to pay as a royalty and yet be able to make, use or sell the patented article in the market at a reasonable profit. *See Wang Labs. v. Toshiba Corp.*, 993 F.2d 858, 870 (Fed.Cir.1993) (citation omitted). When an established royalty does not exist, a reasonable royalty may be determined based on "hypothetical negotiations between [a] willing licensor and [a] willing licensee" at the time that the infringement began. *Id.* (citation omitted). Although a "trier of fact must have some factual basis for a determination of a reasonable royalty," consideration of a hypothetical negotiation "necessarily involves an element of approximation and uncertainty." *Unisplay, S.A. v. Am. Elec. Sign Co.*, 69 F.3d 512, 517 (Fed.Cir. 1995).

Because the court finds that Cordis is estopped from asserting equivalence of the "plurality of slots formed therein" limitation of claims 23, 51 and 54 of the '762 patent and claims 1 and 3 of the '984 patent, the parties' motions regarding the damages portion of the AVE trial are moot, and BSC's motion for a new damages trial is granted so that the AVE stents may be considered as non-infringing alternatives to the NIR stent.

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VI. UNENFORCEABILITY

A. Findings of Fact, Pursuant to Fed.R.Civ.P. 52(a)

1. The '762 Patent

1. **Contention.** AVE and BSC contend that the '762 patent is unenforceable because the patentee committed inequitable conduct by presenting false and misleading arguments to distinguish Ersek during the first reexamination of the parent '665 patent and during the '762 reexamination.

2. **Facts of record.** In his 1983 monograph entitled "Expandable Vascular Endoprosthesis," Dr. Palmaz described the slotted tube configuration as follows:

> The tube could initially be a thin walled silver, tantalum or stainless steel continuous tube in which alternating fissures such as shown in Fig. 1 have been done. This process may require sophisticated techniques such as electronic or laser etching. **After expansion, the unfolded "bars" between fissures will twist and loss of length will result.** Although the expanded tube wall will be thicker than the wire mesh tube the unexpanded tube wall will be smoother and thinner therefore allowing an easier introduction and positioning before inflation.

(PX 1557 at 6) (emphasis added)

3. The '665 patent was filed in November 1985. Although Figures 2A and 2B appear to be smooth, none of the claims of the original '665 patent address this feature. (PX 1)

4. The '762 patent was filed in November 1986. Figures 1A and 1B show smooth first and second diameters, and original claim 23 expressly calls for a smooth first diameter. The second diameter is described in the specification as "relatively smooth." (PX 3, col. 7, lns. 41-45)

5. The early prototypes of the slotted tube invention were rigid and resulted in distortion and twisting upon expansion. (D.I. 1052 at 266-67; D.I. 1054 at 617) The distortion was minimized when an annealing process was applied to the devices. (D.I. 1054 at 652)

6. The '665 patent was submitted for reexamination in 1991, after Ersek was found. (PX 8, Tab 7; PX 12, Tab 6 at 1463) Claim 13 of the '665 patent was amended to include a "tubular shaped member having a second, expanded diameter and a substantially smooth outer wall surface." (PX 9, Tab 73 at 2184) The examiner initially rejected the amendment because,

> as the Palmaz graft (each embodiment) is expanded and the openings 82 are widened, the forces acting on the graft are similar to that described in Ersek in col. 2, lines 63-75 and col. 3, lines 1-6. The Palmaz elongated members 75, 76 would inherently twist so that

> the narrow edges of the Figs. 2A, 2B bars, for example, would face outwardly and thus preclude the outer surface from fairly being characterized as "smooth" or "substantially smooth."

(*Id.*, Tab 68 at 2149)

7. In response, the patentee submitted the declaration of John S. Kula, dated March 11, 1993. In his declaration, Mr. Kula averred that, "[w]hen the graft/prosthesis of the Palmaz '665 Patent is expanded to **its maximum design specification diameter**, the outer wall surface of the graft/prosthesis remains substantially smooth." (*Id.*, Tab 81 at 2252) (emphasis added) The examiner, in allowing amended claim 13 over Ersek, relied on the Kula declaration as evidence "that the elongated members 75, 76 of the embodiment of figs. 2A and 2B of the Palmaz '665 patent do not inherently twist when the graft is expanded." Therefore, the "outer surface of the graft shown in the Palmaz '665 patent is smooth." (*Id.*, Tab 89 at 2282) The examiner also relied on his examination of PX 3986 and PX 3987, models of the Palmaz and Ersek stents, respectively.[23] (*Id.*)

8. Ersek also was reviewed during the course of the '762 reexamination, filed in October 1997. (PX 12) In

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23. The aspect ratio (the ratio of the width of the strut to the strut's thickness, in the cross-section) of the Palmaz peripheral stent (PX 3986) was 1.15, in contrast to the Ersek model's aspect ratio of 4.87 (PX 3987). (D.I. 1052 at 48-49)

comparing dependent claim 23 of the '762 patent to Ersek, the patentee declared:

> The Ersek fixation sleeve does not have a substantially uniform wall thickness, nor is it thin walled. The expanded metal sleeve is twice as thick in some areas as in others, and the thickness of the wall varies throughout. The fixation sleeve is deliberately formed to provide a multitude of narrow projecting edges (Figure 5) that are intended to embed themselves into the tissue wall upon expansion of the sleeve. These sharp metal projecting and penetrating edges are a fundamental requirement for the successful operation of the fixation sleeve. Thus, the periphery of the Ersek sleeve is rough, sharp, and not smooth.

(PX 13, Tab 37 at 3079; *see also id.*, Tab 36 at 3049-50; PX 12, Tab 4 at 1416, 1436)

9. The examiner ultimately allowed claim 23, finding that

> the outside of the wall surface of the Ersek (3,657,744) fixation sleeve is not considered to be smooth. The Ersek fixation sleeve is formed of expanded metal. A sample of conventional expanded metal was shown to the examiner during the July 8, 1998 interview. The sample is depicted in Exhibit 1 of the July 22, 1998 amendment. The sample

> has the same basic shape as that shown in figure 5 of Ersek. As one follows the outside surface of one of the strands of the sample, one meets an abrupt obstacle at the bridge (at the junction of the strands) since the bridge has a thickness which is twice as great as the strand. The outside of the wall surface of the Ersek fixation sleeve includes a multitude of these obstacles (one at each bridge), making it rough rather than smooth. Therefore, the Ersek reference fails to meet the smooth surface limitation quoted above. Further, making the outside of the Ersek fixation sleeve smooth rather than rough would be contrary to the teachings of Ersek since the rough surface formed by narrow outwardly projecting edges is intended to embed itself into the tissue wall upon expansion of the sleeve (col. 3, lines 1-6).

(PX 14, Tab 58 at 3258)

10. According to the evidence of record, some degree of twisting is inherent in the design of the Palmaz and Palmaz-Schatz slotted tube stents upon the application of torsional force. The degree of twisting will depend on a number of factors, including the aspect ratio selected by the designer and the extent of expansion exercised by the cardiologist. (D.I. 1052 at 24-46, 68-69, 143-44, 214, 227-35, 280-85; D.I. 1053 at 358, 367-68; D.I. 1054 at 625-28, 659-60; PX 3989-A) With respect to the former factor, a large aspect ratio will show a greater

degree of twisting for a given amount of expansion force. (D.I. 1052 at 48-49) With respect to the latter factor, the greater the expansion, the greater the tendency to twist. (*Id.* at 68-69) Cardiologists tend to overexpand the Palmaz and Palmaz-Schatz stents in order to take into account the recoil characteristics of such stents and to secure the stents in the vessels by embedding.[24] (D.I. 1052 at 44-45, 236-38; D.I. 1054 at 685-86) Therefore, even when these factors (aspect ratio, degree of expansion) are controlled, some degree of twisting can be detected in the Palmaz and Palmaz-Schatz stents, to wit: some struts of the stent will be twisted, some will not be, some will be twisted more than others. (D.I. 1052 at 39, 227-31) The twists, however, are "very, very small." (*Id.* at 27)

11. The record demonstrates that twisting is a desired feature in the Ersek fixation sleeve (the resulting "narrow projecting edges" are intended to embed themselves into the tissue wall upon expansion of the sleeve). In contrast, twisting is an undesired feature of the expanded Palmaz and Palmaz-Schatz stents, as twisting causes "microturbulence" and damage to the arterial wall which increase the risk of thrombus formation and of restenosis. (D.I. 1054 at 648-49, 690-91)

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24. In contrast to the Ersek device, the edges of which must penetrate the tissue of the wall in order to function as designed (not to expand a lumen, but to replace a surgeon's sutures), the struts of the Palmaz and Palmaz-Schatz stents are ultimately "buried" on all three sides by the tissue of the lumen due to the pressure of expansion. (D.I. 1054 at 661, 744-47)

12. The clinical experience with the Palmaz and Palmaz-Schatz stents is not consistent with any significant degree of twisting, as they have performed well with low restenosis rates. (D.I. 1052 at 277-79; D.I. 1054 at 648-49, 690-91)

13. By the early 1990s, Dr. Palmaz did not believe that the struts of the Palmaz and Palmaz-Schatz stents "inherently twisted" but believed, instead, that the surface of said stents, as expanded, was "substantially smooth." (D.I. 1054 at 656-60)

2. The '984 and '332 Patents

14. **Contention.** AVE and BSC contend that, during the prosecution of the '417, '984 and '332 "connected stent" patents, the patentees concealed and misled the United States Patent and Trademark Office ("PTO") regarding material "connected Z stent" art.

15. **Facts of record.** Dr. Palmaz became aware of connected Z stents in the mid-1980s and followed the work thereafter. (D.I. 1053 at 565-67) Dr. Schatz began working with Dr. Palmaz in the summer of 1985. (D.I. 1054 at 699) Starting in 1985, Dr. Palmaz shared with Dr. Schatz and with their counsel, Ben D. Tobor, articles on stenting. (*Id.* at 662-63, 699) By 1988, Mr. Tobor knew of the existence of journals such as *Radiology* and knew where he could access information for patent prosecution searches. (D.I. 1053 at 600) By the late 1980s, stent research had progressed to the point where research papers were presented by the

character of the stent, as opposed to all stent research being grouped together. (*Id.* at 567)

16. **The '417 patent.** The application for the '417 patent was filed in March 1988. (PX 15, Tab 7) On March 26, 1988, Dr. Palmaz acknowledged his duty to disclose material information of which he was aware to the patent examiner. (*Id.*, Tab 9)

17. In response to an office action rejecting claims 1-24 (*Id.*, Tab 11), Mr. Tobor argued in February 1989 that:

> Applicant would agree with the Examiner's reasoning and basis for rejection if independent Claims 1 and 17 did not include the method step of "disposing at least one connector member between adjacent prostheses to flexibly connect adjacent prostheses to each other." This step, and claim limitation, does not read merely on "adding additional prosthesis" as contended by the Examiner, but requires some physical connection between discrete prostheses or intraluminal grafts, the physical connection being "at least one connector member." Thus, the issue is not whether or not it would be obvious to use a plurality of prostheses or intraluminal grafts, but whether or not it would be obvious to practice a method, which not only uses a plurality of prostheses, or grafts, but also physically connects adjacent

prostheses, or grafts to one another with a connector member.

To illustrate this issue, Applicant would call Examiner's attention to U.S. Patent No. 4,580,568, issued April 8, 1986, in the name of C. Gianturco, for a percutaneous endovascular stent method for insertion thereof. . . . With respect to the Gianturco '568 patent, this patent teaches the use of a plurality of prostheses or stents, as shown in FIGS. 7 and 8. Applicant would agree that this patent provides a teaching of the use of multiple stents although Applicant seriously questions its efficacy and operability when using multiple stents. However, this is not to say that Gianturco provides a teaching or suggestion of Applicant's methods wherein a connector member is disposed between adjacent prostheses, stents, or intraluminal grafts.

The extensive number of references cited against Applicant's prior patents were virtually all brought to the attention of the prior Examiner by Applicant, and virtually all of the cited references relate to stents, prostheses, or intraluminal grafts. To the best of Applicant's knowledge, and the knowledge of the undersigned counsel, other than the Gianturco '568 patent, none of the other cited references in the Palmaz '762 and '665 patents

> utilize a plurality of stents, grafts, or prostheses in the methods disclosed in those patents and publications. But for the Gianturco '568 patent, it would appear that the art teaches away from using more than one prosthesis. With the Gianturco '568 patent, Applicant submits that the most that can be said is that one patent teaches the use of a plurality of stents; however, the stents are not connected by a connector member, nor are the plurality of stents inserted into the body passageway at the same time as in Applicant's method.

(PX 15, Tab 15 at 81-83; *see also id.*, Tab 33 at 152)

18. By February 1989, multiple journal articles had been published regarding connected Z stents. (*See* PX 3207; AVEX 364; AVEX 359; AVEX 438; AVEX 671; AVEX 1953) At least one such article (PX 3207) was cited as a reference in a January 1988 article for which Drs. Palmaz and Schatz were given credit for authorship. (PX 4049) Dr. Palmaz was aware of these publications. (D.I. 1053 at 587-99)

19. Sometime in 1989, Dr. Palmaz forwarded to Mr. Tobor a copy of Yoshioka (AVEX 438) as a "pertinent reference" regarding a "stent graft idea," not in connection with the '417 patent prosecution. At the time, Dr. Palmaz did not believe that connected Z stent art was relevant to the '417 patent: connected Z stents had a stabilizer bar between the stents to add rigidity (i.e.,

to keep them in a rigid position and in place after delivery), while the connector of the '417 patented invention added flexibility. (D.I. 1054 at 664-68)

20. In May 1991, Mr. Tobor brought Yoshioka to the attention of the '417 examiner. Mr. Tobor declared that he did not believe the article was prior art, but was bringing it to the examiner's attention "out of an abundance of caution." The article was described by Mr. Tobor as follows:

> The enclosed article to Yoshioka, et al., discloses an arterial endovascular graft constructed by wrapping an expandable nylon mesh around a framework of Gianturco self-expanding metallic stents. "Three or four stents were connected in tandem by metallic struts constructed from the same wire."

(PX 15, Tab 48) Dr. Palmaz does not recall reading this declaration, although he may have been aware of the "argument." (D.I. 1053 at 574-81)

21. The '417 patent issued on April 7, 1992. (PX 15, Tab 58)

22. **The '984 patent**. The application for the '984 patent was filed in October 1988. (PX 16, Tab 10) On September 30, 1988, Dr. Schatz acknowledged his duty to disclose material information of which he was aware to the patent examiner. (*Id.*, Tab 11)

23. The '984 patent was assigned to EGP. (*Id.*, Tab 8) Drs. Palmaz and Schatz were two of the three partners of EGP. Although Dr. Palmaz was consulted about background literature and prior art identified in the '984 patent, he believed that it was Dr. Schatz's responsibility to fulfill the duties of full disclosure in connection with the '984 patent. (D.I. 1053 at 562-63)

24. In response to an office action rejecting claims 1-6 (PX 16, Tab 16), Mr. Tobor argued in February 1990 that

> Gianturco, the only reference known to Applicant which teaches the use of a plurality of grafts, or stents, has **at most** a teaching of the use of a plurality of stents; however, the stents are not connected by a connector member, flexible or otherwise, nor is any connector member, such as claimed in the present application, disclosed, taught or suggested.

(*Id.*, Tab 22 at 523) (emphasis in original)

25. In December 1990, Mr. Tobor brought Yoshioka to the attention of the '984 examiner, stating:

> It is not believed that the enclosed publication is prior art as against the present application in that the publication date of the publication is "October 1988," and the present application was filed October 4, 1988.

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> This publication discloses an endovascular stent graft consisting of an expandable nylon cylinder supported by a framework of self-expanding stents. "Three or four stents were connected in tandem by metallic struts constructed from the same wire. The first stent was the lead stent, which acted as an anchor for the graft."

(*Id.*, Tab 36)

26. Dr. Schatz testified that he has no independent recollection of knowing about connected Z stent references prior to July 1991. (D.I. 1054 at 706-17; PX 3996)

27. The claims of the '984 patent were allowed in August 1992. (PX 16, Tab 62)

28. **The '332 patent.** The application for the '332 patent was filed in November 1992 as a continuation of the '984 patent. (PX 17, Tab 4) Dr. Schatz resubmitted his September 30, 1988 declaration acknowledging his duty of disclosure. (*Id.*, Tab 5)

29. In March 1993, in response to an office action rejecting claims, Mr. Tobor argued that Yoshioka

> does not disclose the subject matter for which the Examiner relies upon this article. All Yoshioka et al. has to say about connecting stents is that they "were connected in tandem

by metallic struts constructed from the same wire." The article does not say how many metallic struts were utilized, where they were connected, their angular disposition, whether or not they were flexible, or any other details of construction. . . .

Assuming that Yoshioka et al. can be used as a reference, the rejection is still deficient for the following reasons. Neither Wiktor nor Yoshioka et al. discloses a plurality of "thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member" and "only one connector member being disposed between adjacent tubular members to flexibly connect the adjacent members." . . .

In summary, with respect to the rejection based upon Wiktor and Yoshioka et al., assuming Yoshioka et al. is properly available as a reference, neither of these references discloses the particular claimed tubular members which are flexibly connected by only one connector member as claimed by Applicant.

(*Id.*, Tab 11 at 2845-46)

30. In October 1994, in connection with Patent Interference No. 103,432, Mr. Tobor argued that the claims of United States Patent No. 5,104,404, filed in June 1991 (the "Wolff patent") were unpatentable over Yoshioka:

> Yoshioka discloses a plurality of tubular shaped stents formed of stainless-steel wire, wherein "three or four stents were connected in tandem by metallic struts constructed from the same wire" as shown in Fig. 1. As seen in Fig. 1 of Yoshioka, a single wire is disposed between the stents to "hinge" the stent segments together. Accordingly, Yoshioka clearly anticipates all of the claims of the Wolff '404 Patent which correspond to Count 1.

(BSCX 6759 at 2-3) The Wolff patent describes, e.g., a number of stents connected together by hinges (the hinges can be either straight or coiled wire) welded in place to provide articulation between the stent segments.

31. On March 21, 1996, Dr. Schatz submitted a declaration in connection with Patent Interference No. 103,432 regarding Yoshioka:

> I have been informed that this article was publicly available prior to October 1988.
>
> Based upon my review of and study of the Yoshioka article and based upon my extensive

> experience in the design, testing and use of various stents, including the stents of Schatz Exhibit No. 1 and the '667 application and those of Schatz Exhibit No. 3, it is my opinion that the Yoshioka article, Schatz Exhibit No. 11, teaches, discloses, and describes an articulated self-expanding separate stent comprising at least two stent segments, each stent segment having a generally tubular shape . . . , and a hinge means extending between and connecting adjoining stent segments, whereby the stent segments may flex and articulate about said hinge means to provide support for curved blood vessels.

(PX 106 at 8-9) At the time Dr. Schatz submitted this declaration, he "assumed" that the bar connecting the two Z stents was flexible. (D.I. 1054 at 717-19) Dr. Palmaz never agreed with the above description. (*Id.* at 684)

32. On December 2, 1998, Mr. Tobor presented new independent claims 26, 37 and 46 that were "specifically drafted to cover certain commercial competitive products[25] and to avoid the issues of patentability raised during" Interference No. 103,432. (PX 17, Tab 32 at 2933-34) In this submission, Mr. Tobor addressed the "prior art and other materials identified and discussed during Interference No. 103,432," including Yoshioka.

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25. Certain of claims 26-36 were intended to cover AVE's MicroStent II and GFX stents, while certain of claims 46-54 were intended to cover BSC's NIR stent. (PX 17, Tab 32 at 2940)

(*Id.* at 2938-39) Specifically, Mr. Tobor distinguished the connected Z stent references as follows:

> As the Examiner is well aware, it is improper to combine references unless there is some teaching or suggestion in the prior art for the contemplated combination. . . .
>
> During the above mentioned interviews, Examiner Brittingham recognized the differences between balloon expandable stents, like those of the present application, and self-expanding stents, like those of the connected Gianturco Z-stent publications, and expressly acknowledged that it would be improper to combine references relating to self-expanding stents with references relating to balloon expandable stents, because of such differences.
>
> There is clearly no teaching or suggestion to combine either the self-expanding stents disclosed in the connected Gianturco Z-stent publications or the coiled wire stent disclosed in the Wiktor patent with the stents disclosed in the Palmaz patents in a manner that would create the structures defined in claims 26, 37 and 46. The sole basis for any such combination is impermissible hindsight gleaned from applicant's disclosure of his invention. At the time of the invention, there was no suggestion or teaching to interconnect

> a plurality of balloon expandable, plastically deformable segments as defined in the claims in a manner that would permit the segments to be displaced at an angle with respect to the longitudinal axis of an adjacent segment when the stent is delivered through a curved portion of an access or coronary artery.

(*Id.* at 2942-43)

33. The claims of the '332 patent were allowed on December 22, 1998. (PX 17, Tab 37)

3. The '312 and '370 Patents

34. **Contention.** BSC contends that, during the prosecution of the '312 patent, the patentees failed to disclose a reference they knew, or should have known, would have been material to the PTO's consideration of the patent application.

35. **Facts of record.** The application for the '312 patent was filed in February 1994 by Robert E. Fischell, David R. Fischell, and Tim A. Fischell. (PX 5003, Tab 9) Dr. Robert Fischell began working on the invention of the '312 patent in 1993 and, at that time, began collecting articles and patents about stents. (D.I. 1054 at 825, 843-46) Initially, Dr. Fischell prosecuted the patent himself. (PX 5003, Tab 9) At the time the '312 application was filed, Dr. Fischell had personally prosecuted more than twenty patents and was fully aware of the duty of disclosure. (D.I. 1054 at 830-31)

36. Only claim 8 of the '312 patent as originally filed mentioned longitudinals having an undulating shape. (PX 5003, Tab 8 at 26) By March 1995, amended claims 24, 26 and 27 described longitudinals having "an undulating shape" or "an undulating structure." (*Id.*, Tab 20 at 66-67) The undulating feature was considered an important way of distinguishing the prior art. (D.I. 1054 at 838; *D.I. 196 at 526-27; *D.I. 197 at 818-19)

37. On July 17, 1995, the attorney prosecuting the European counterpart to the '312 patent, Morton J. Rosenberg, forwarded to Dr. Fischell the "Search Report from the European Patent Office." Mr. Rosenberg noted that

> the only reference which is stated as being particularly relevant to Claim 1 is European Patent Application # 579523 whose inventor is Jean-Claude Sgro. We have made a Patentee Search to determine whether we have any corresponding patent in the United States but have come up negatively. It may pay us to make a translation from the French to determine if this is relevant.

(BSCX 11021)

38. As was the case with the original '312 application, the only claim in the European application which mentioned undulating longitudinals was claim 8. (BSCX 11413)

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39. In addition to the Sgro reference, among the references mentioned in the European search report and forwarded by Mr. Rosenberg to Dr. Fischell was United States Patent No. 4,856,516 (the "Hillstead patent"), which was noted as a "Y" reference relevant to claim 8. (BSCX 10003, 10004) A "Y" reference is a reference that is particularly relevant if combined with another document of the same category. (D.I. 1055 at 959-64)

40. The Hillstead patent is directed to a stent constructed as described in claim 1 of that patent:

> A stent for reinforcing a vessel within a subject comprising a cylindrical support dimensioned to fit within an interior of said vessel constructed from an elongated wire bent to define a series of relatively tightly spaced convolutions or bends, said wire also bent in the form of a plurality of loops spaced along an axial dimension of the stent and connected by a series of half hitch junctions where each of the plurality of loops includes a number of said regularly spaced convolutions around its circumference, said stent being radially expandable from a first outer diameter which fits within said vessel to a second increased diameter which contacts an inner wall surface of said vessel to reinforce said inner wall.

(PX 5313, Ex. D, col. 4, lns. 37-50; BSCX 10045) According to the specification, the "resultant structure has a high

degree of flexibility." (PX 5313, col. 2, ln. 21) Reproduced below is Figure 2A, displayed on the cover page of the Hillstead patent.

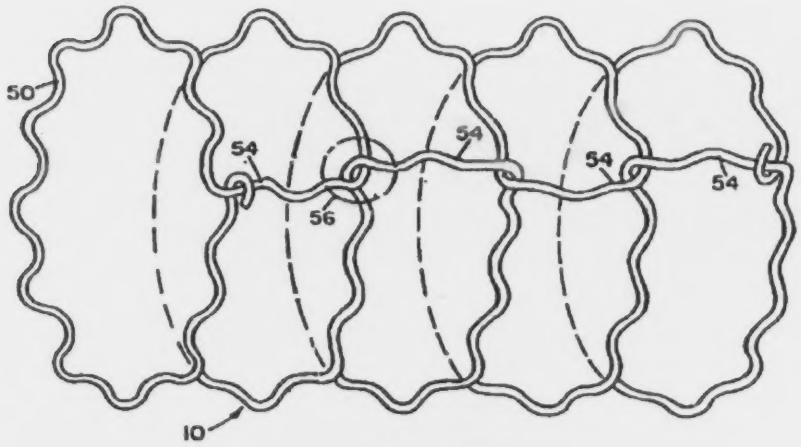

FIG. 2A

41. In December 1995, Dr. Fischell saw stents with undulating longitudinals at the Thorax Center Conference in Rotterdam. His exposure to such stents "heightened [his] perception of the value of claims on undulating longitudinal structures for stents because they enhance flexibility." (D.I. 1054 at 855-57)

42. Also in December 1995, the PTO informed Dr. Fischell that the file wrapper for the '312 patent application could not be located. (PX 5003, Tabs 22, 23) Dr. Fischell himself and through his newly hired attorney, Mr. Rosenberg (*Id.*, Tab 25), submitted a duplicate file that had been maintained by Dr. Fischell.

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(*Id.*, Tabs 21, 24) When the application submitted in the duplicate file (*Id.*, Tab 8 at 24) is compared with the original application (preserved by the PTO on microfilm), there is a difference of one sentence (emphasized below) contained in the latter and omitted from the former:

> It is further anticipated that a pre-deployment stent structure 20 as shown in FIG. 9 could be formed from a thin-walled cylindrical tube whose inside diameter is slightly smaller than the outside diameter of the balloon 6 shown in FIG. 6. A pattern such as that shown in either FIG. 6 or FIG. 7 could be photoetched onto a thin-walled metal cylinder. The one piece structure 20 shown in FIG. 9 has folded ovals 22 and longitudinals 23T, 24B, 24R and (not shown) 24L. This pre-deployment stent structure 20 could then be mounted onto the expandable balloon; the stent having sufficient elastic recoil to firmly grasp down onto the balloon. **Another method to form the pre-deployment stent is by etching the correct pattern onto a thin, flat metal plate, then forming a tube from that plate and then making a longitudinal weld to form a cylindrically shaped structure which is, in fact, the pre-deployment stent structure 20 shown in FIG. 9.**

(BSCX 12011 at 9) (emphasis added) As it happens, the NIR stent is made according to the method described in the emphasized language above.

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43. In March 1996, the Fischells, through their company, IsoStent, Inc., entered into a collaboration agreement with Johnson & Johnson whereby Johnson & Johnson would fund IsoStent's stent development and would receive an option to buy IsoStent for more than $20 million. (D.I. 1054 at 854) By March 1996, the Fischells had decided they wanted the claims of the '312 patent to cover all stents with undulating longitudinals, whether such stents had rings or not. (*Id.* at 857-58)

44. In June and July of 1996, the patentees filed a supplementary amendment, an information disclosure statement, and a list of patents and publications discussed in the information disclosure statement. (PX 5003, Tabs 29, 30 and 31) The supplementary amendment identified new claims 28 and 29 which featured undulating longitudinal structures. (*Id.*, Tab 29 at 80) The references listed in the information disclosure statement were distinguished as not having undulating longitudinals. (*Id.*, Tab 30 at 85-86) The Hillstead patent was not identified in any of these submissions. (*Id.*, Tabs 30, 31)

45. An amendment was filed by Mr. Rosenberg in November 1996. (*Id.*, Tab 36) Claims 1, 13, 15, 21, 22, and 23 were amended to add language requiring that the longitudinals of the stent have an "undulating shape" or an "undulating contour for enhancing longitudinal flexibility." (*Id.* at 99-102) The applicants distinguished the prior art, including the Sgro reference, on the ground that such art did "not provide for the undulating shape or contour of the 'longitudinals' of the subject Patent Application system." (*Id.* at 105-106)

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46. The '312 patent issued on July 1, 1997. (PX 5003, Tab 1)

47. Through a series of transactions in 1998 and 1999, Cordis Corporation acquired certain assets of IsoStent and agreed to assume certain of IsoStent's obligations to the Fischells, including consulting agreements and royalty payments under, *inter alia*, the '312 patent. (BSCX 10953; D.I. 1054 at 830)

48. Dr. Fischell and Mr. Rosenberg testified that they did not look at the Hillstead patent until April 1998, despite both having copies of said reference in their respective files since at least July 1995. (D.I. 1054 at 849-50, 882-89, 914-16; D.I. 1055 at 955, 978-80, 995) The evidence indicates that neither took responsibility for conducting a prior art search directed to the added limitation of "undulating" longitudinals, despite their experience in the field and their focus on the limitation.

49. In May 1998, Dr. Fischell identified the Hillstead patent (along with some sixty other references) as relevant prior art in connection with the '370 patent. (D.I. 1054 at 889-90, 921-25; D.I. 1055 at 980; PX 5002, Tab 16 at 191)

B. Conclusions of Law, Pursuant to Fed. R. Civ. P. 52(a)

1. "Applicants for patents are required to prosecute patent applications in the PTO with candor, good faith, and honesty." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172,

1178 (Fed.Cir.1995). The duty to prosecute patent applications with candor, good faith, and honesty "rests on the inventor, on each attorney or agent who prepares or prosecutes an application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application." *Id.* at 1178 n. 6.

2. "The duty of candor extends throughout the patent's entire prosecution history. In determining inequitable conduct, a trial court may look beyond the final claims to their antecedents. 'Claims are not born, and do not live, in isolation. Each is related to other claims, to the specification and drawings . . . [and] to earlier or later versions of itself in light of amendments made to it.' . . . Therefore, a breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application." *Fox Indus., Inc. v. Structural Preservation Sys., Inc.*, 922 F.2d 801, 803-04 (Fed.Cir.1991).

3. A charge of inequitable conduct includes within its scope "affirmative misrepresentation of a material fact, failure to disclose material information, or submissions of false material information, coupled with an intent to deceive." *Molins PLC*, 48 F.3d at 1178.

4. "A holding of inequitable conduct requires proof by clear and convincing evidence. This proof must include a threshold showing of both materiality and

intent to mislead or deceive the patent examiner." *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1261 (Fed.Cir.2001) (citing *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 551 (Fed.Cir.1990)).

5. "Information is 'material' when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." *Molins PLC*, 48 F.3d at 1179. A reference will not be considered material if it is not as relevant as that actually considered by the examiner or if it is merely cumulative of the information considered by the examiner. *See id.* "Information concealed from the PTO may be material even though it would not invalidate the patent. . . . As stated, the test for materiality is whether a reasonable examiner would have considered the information important, not whether the information would conclusively decide the issue of patentability." *Li Second Family Ltd. P'ship v. Toshiba Corp.*, 231 F.3d 1373, 1383 (Fed.Cir.2000), *cert. denied*, 533 U.S. 929, 121 S.Ct. 2550, 150 L.Ed.2d 717 (2001).

6. "Intent" commonly means "a state of mind in which a person seeks to accomplish a given result through a course of action." *Molins PLC*, 48 F.3d at 1180 (citing *Black's Law Dictionary* at 810 (6th ed.1990)). "Intent need not be proven by direct evidence; it is most often proven by a showing of acts, the natural consequences of which are presumably intended by the actor." *Id.* "For example, intent may be inferred where a patent applicant knew, or should have known, that

withheld information would be material to the PTO's consideration of the patent application." *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed.Cir.1997).

7. "If the threshold requirements of materiality and intent are established, 'those fact findings are balanced to make the determination whether the scales tilt to a conclusion that inequitable conduct occurred.' . . . 'The more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and visa versa.' . . . If, however, either materiality or intent is not found, then no further analysis need be performed and unenforceability must be denied.' " *Monon Corp.*, 239 F.3d at 1261 (citations omitted).

8. "It is not inequitable conduct to omit telling the patent examiner information that the applicant in good faith believes is not material to patentability." *Allied Colloids, Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1578 (Fed.Cir.1995). Disclosure of relevant prior art to the PTO during the course of another, subsequent patent prosecution "has no bearing on whether [the patentee] acted with deceptive intent during prosecution of the" application at issue. *Li Second Family Ltd. P'ship*, 231 F.3d at 1381.

9. "Because the adjudication of an inequitable conduct claim is an equitable determination, it is committed to the discretion of the trial court." *Monon Corp.*, 239 F.3d at 1261.

10. **The '762 patent**. The court concludes that AVE and BSC have not carried their burden of proving by clear and convincing evidence that the patentee intended to deceive the PTO concerning a material fact. The "material fact" identified by AVE and BSC is that the struts of the Palmaz and Palmaz-Schatz stents "inherently twist." The patent examiner, however, started from that premise. The question before the court, therefore, is whether the submissions made by the patentee in response to the examiner's premise were materially false and meant to be so. The court finds neither to be the case. As evidenced by the record, whatever small degree of twisting that occurs upon expansion of the Palmaz and Palmaz-Schatz stents is meant to be minimized (as distinguished from the Ersek reference) and has been minimized by engineering and production solutions. The patentee believed at the time of the submissions, and continues to believe, that the outer surface of the Palmaz and Palmaz-Schatz stents is "substantially smooth" in the second diameter. Therefore, the threshold levels of materiality and intent have not been demonstrated by clear and convincing evidence. Even had AVE and BSC carried their burden of proof, it is the court's equitable judgment that the patentee's conduct was not so culpable that the '762 patent should not be enforced.

11. **The '984 and '332 patents**. The court concludes that AVE and BSC have not carried their burden of proving by clear and convincing evidence that the patentee failed to adequately disclose material information—the connected Z stent art—to the PTO

and intended to deceive the PTO in this regard. There is no question but that the connected Z stent art was before the PTO in all three related patents—the '417, the '984 and the '332 patents—before any of the patents issued. Although the patentee could have brought Yoshioka or a similar reference to the attention of the PTO earlier than he did, nevertheless, the PTO had the opportunity to consider the prior art before allowing any of the claims at issue. The fact that the patentee's arguments changed[26] over time does not demonstrate (in the court's view) an intent to deceive. Once again, even had the threshold levels of materiality and intent been demonstrated by clear and convincing evidence, in weighing materiality and intent, it is the court's equitable judgment that the patentee's conduct was not so culpable that the '984 and '332 patents should not be enforced.

12. **The '312 patent and '370 patents.** The court concludes that BSC has carried its burden to prove by clear and convincing evidence the threshold levels of materiality and intent with respect to nondisclosure of the Hillstead patent. By the time the '312 patent issued, the patentees considered the most significant invention disclosed in the '312 patent to be undulating longitudinals. The only prior art reference identified in the record that disclosed undulating longitudinals was

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26. Initially, the focus was on whether any prior art disclosed connectors between a plurality of stents. Once such prior art references were found, the focus shifted to the type of connector (flexible or not) and the type of stent (balloon expandable or self-expanding).

the Hillstead patent. The patentees purposefully neglected their responsibility of candor to the PTO by "putting their heads in the sand" regarding prior art related to their newly added limitation. The court concludes that the threshold levels of materiality and intent have been demonstrated by virtue of the patentees' increasing emphasis on undulating longitudinals during the course of the '312 patent prosecution and the fact that patentees knew, or should have known, that the Hillstead patent would be material to the PTO's consideration of the '312 patent application. The court further concludes that the submission to the PTO of the Hillstead patent during the '370 patent prosecution has no bearing on whether the '312 patentees acted with deceptive intent during the '312 prosecution. The court finds that the '370 prosecution is tainted by the lack of candor exhibited during the '312 prosecution, since the Hillstead patent was submitted along with sixty other references and never addressed by the patentees. In light of all the circumstances, the court concludes that the patentees' conduct was sufficiently culpable that the '312 and '370 patents should be held unenforceable.[27]

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27. The court finds that BSC has failed to prove by clear and convincing evidence that the "missing sentence" in the '312 application was either material or intended to deceive the PTO.

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VII. CONCLUSION

For the reasons stated, AVE's motion for judgment as a matter of law is granted as to prosecution history estoppel on the "plurality of slots formed therein" limitation of claims 23, 51 and 54 of the '762 patent and claims 1 and 3 of the '984 patent. The parties' motions for a new AVE trial are denied as moot.

BSC's motions for judgment as a matter of law are granted as to prosecution history estoppel on the "substantially uniform thickness" limitation of claim 23 of the '762 patent and no literal infringement of claims 25 and 26 of the '370 patent, and denied as to all other issues. Cordis' motion for judgment as a matter of law against BSC is denied. BSC's motion for a new damages trial is granted.

The court finds that the '762, '984 and '332 patents are enforceable, and the '312 and '370 patents are unenforceable.

An appropriate order shall issue.

APPENDIX D — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING DECIDED APRIL 9, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2006-1393, -1394, -1395, -1396, -1415, -1416

CORDIS CORPORATION,

Plaintiff-Cross Appellant,

v.

MEDTRONIC AVE, INC.,

Defendant-Appellant,

and

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Defendants-Appellants.

Appendix D

MEDTRONIC AVE, INC.,

Plaintiff-Appellant,

v.

CORDIS CORPORATION, JOHNSON AND JOHNSON, and EXPANDABLE GRAFTS PARTNERSHIP,

Defendants-Appellees.

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Plaintiffs-Appellants,

v.

ETHICON, INC., CORDIS CORPORATION, and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants-Cross Appellants.

Appeals from the United States District Court for the District of Delaware in consolidated cases 97-CV-550, 97-CV-700, and 98-CV-19, Judge Sue L. Robinson.

Appendix D

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellants, Boston Scientific Corporation, et al., and a response thereto having been invited by the court and filed by the Cross-Appellant and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on April 16, 2008.

FOR THE COURT,

/s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 04/09/2008

Appendix D

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2006-1393, -1394, -1395, -1396, -1415, -1416

CORDIS CORPORATION,

Plaintiff-Appellant,

v.

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Defendants-Appellants.

MEDTRONIC AVE, INC.,

Plaintiff-Appellant,

v.

CORDIS CORPORATION, JOHNSON AND JOHNSON, and EXPANDABLE GRAFTS PARTNERSHIP,

Defendants-Appellees.

Appendix D

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Plaintiffs-Appellants,

v.

ETHICON, INC., CORDIS CORPORATION, and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants-Cross Appellants.

Appeals from the United States District Court for the District of Delaware in consolidated cases 97-CV-550, 97-CV-700, and 98-CV-19, Judge Sue L. Robinson.

DECIDED: April 9, 2008

ON PETITION FOR REHEARING

Before BRYSON, *Circuit Judge*, FRIEDMAN, *Senior Circuit Judge*, and, KEELEY, *Chief District Judge*.*

PER CURIAM.

Co-defendants Boston Scientific Corp. and Boston Scientific Scimed, Inc., (collectively, "BSC") have filed a

* Honorable Irene M. Keeley, Chief Judge, United States District Court for the Northern District of West Virginia, sitting by designation.

petition for panel rehearing and for rehearing en banc. Among its arguments, BSC asserts that rehearing is warranted because the panel failed to direct the district court to grant BSC a new trial on the issue of obviousness with respect to claim 44 of U.S. Patent No. 4,739,762 ("the '762 patent") following this court's reversal of the district court's order invalidating that claim on other grounds.

In response, Cordis argues that BSC has waived its argument that claim 44 is obvious. Cordis argues that BSC chose not to raise the obviousness of the '762 patent in the first trial in 2000. After Medtronic's first appeal in this case, to which BSC was not a party, the district court issued an order allowing BSC and Cordis to supplement the record to address the validity of the '762 patent in light of the claim construction of "slots formed therein" adopted by this court in Medtronic's appeal. At the 2005 retrial, BSC asserted a defense of obviousness with respect to claim 23 of the '762 patent, but not with respect to claim 44. Instead, BSC filed a motion in limine to exclude Cordis's evidence with respect to the nonobviousness of claim 44. In its motion, BSC argued that the issue of obviousness as to claim 44 was moot because the district court had found that claim invalid under 35 U.S.C. § 305. BSC stated that the issue of obviousness as to claim 44 would be better addressed if Cordis were to succeed in appealing the district court's decision to invalidate claim 44 under section 305. Cordis nevertheless argues that BSC waived any argument regarding the obviousness of claim 44 because the district court's interlocutory order invalidating claim 44

under section 305 did not preclude BSC from raising the obviousness of claim 44 at the 2005 retrial.

The district court's familiarity with the proceedings in this case puts it in the best position to determine whether BSC's defense of obviousness with respect to claim 44 has been waived and, if not, what further proceedings are appropriate. We issue this supplemental order to make clear that this court's mandate was not intended to resolve the issue of waiver and accordingly does not have the effect of depriving the district court of the authority to determine whether it should conduct further proceedings addressing the merits of the issue of the obviousness of claim 44.

SO ORDERED.